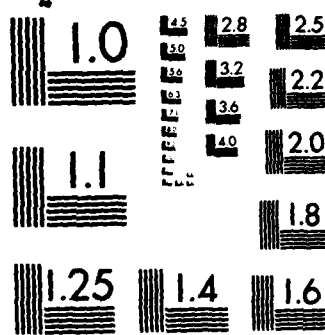


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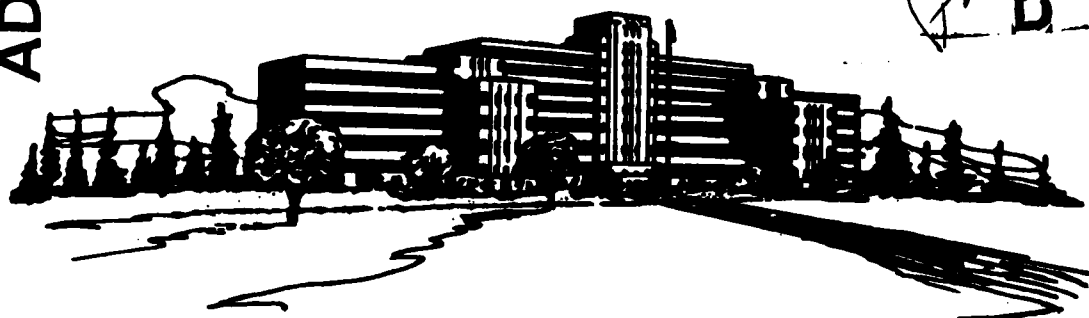
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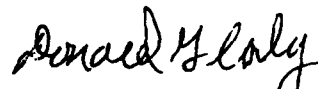
## FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1985 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 70-25, Use of Volunteers as Subjects of Research, and HSC Reg 40-23, as amended, Management of Clinical Investigation Protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations.

In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

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DONALD G. CORBY, M.D.  
Colonel, MC  
Chief, Department of Clinical  
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UNIT SUMMARY

## UNIT SUMMARY

### Clinical Investigation Program, FAMC

Clinical Investigation efforts by FAMC personnel in FY 85 culminated in the publication of 108 articles and 104 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1985, there were 197 research protocols on the DCI register. Of these, 150 projects were ongoing and 47 were new registrations.

#### Objectives:

*The objectives of the program were:*

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center; (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community; To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints; and, To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

*Research activities cover the fields of medicine, surgery, clinical investigation, pediatrics, pathology, radiology.*  
The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e.; active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medicine. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

#### Technical Approach:

This support, direction and management is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7,

*Primary Care, 1  
Emergency Medicine,  
Neurology, and  
General Hospital.*

Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 15-2, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters and other facilities.

Manpower: Current authorized strength is outlined.  
Authorized

<u>Description</u>	Grade	MOS	Br	Auth	Req	Act	Name	Rank
Chief								
Dept Clin Inv	06	60P9B	MC	1	1	1	Corby	COL
C, Micro Svc	04	68A00	MSC	1	1	1	Engelkirk	LTC
Lab Res Mgr	03	68F00	MSC	0	1	1	Quigg	MAJ(P)
C, Biochem Svc	03	68C00	MSC	1	1	0	Verma	CPT
C, Immunol Svc	03	68E00	MSC	1	1	1	Rickman	CPT
C, Cell Phys. Svc.	03	68J00	MSC	1	1	1	Ferris	CPT
C, Animal Res Svc	04	68F00	VC	1	1	1	McCullen	CPT(P)
NOIC-Med Lab	E7	92B4R		1	1	1	Engle	SFC
Sr Med Lab SP	E6	92B3R		1	1	1	Fernandez	SSG
Operating Rm Sp	E5	91D2R		1	1	1	Dugan	SGT
Bio Sci Asst	E5	01H3R		1	1	1	Chadwick	SSG
Bio Sci Asst	E5	01H2R		1	1	1	Jones	SGT
Bio Sci Asst	E5	01H3R		1	1	1	Sanders	SGT
Vet Sp	E6	91T2R		1	2	1	Barrett	SSG
Vet Sp	E4	91T1R		0	0	1	Lamb	PFC
Vet Sp	E4	91T2R		0	0	1	Phillips	PFC
Supv Res Chem	13	1320		1	1	1	O'Barr	

<u>Description</u>	<u>Grade MOS</u>	<u>Br</u>	<u>Auth</u>	<u>Req</u>	<u>Act</u>	<u>Name</u>
Microbiologist	11 0403	GS	2	2	2	Lima Paine
Microbiologist	09 0403	GS	3	6	5	Koester Morse Nelson Tessier Hoyt
Med Technologist	11 0644	GS	0	1	1	Rush
Med Technologist	09				1	Muehlbauer
Med Technician	07 0645	GS	2	2	2	Ramirez Nelson
Research Chem	09 1320	GS	3	4	3	Noble Swanson Feuerstein
Bio Lab Tech (animal)	08 0404 09 0404	GS GS	1 1	1 1	1 1	Jones Mercill
Ed Asst	06 0318	GS	1	1	1	McCrill
Animal Caretaker	05 7706	WG	1	3	2	Slatton Hitchcock
Secretary	06 0318	GS	1	1	1	Montoya

#### Animal Resources Service

The management and staff of the Animal Resources Service continue to make improvements in the operating efficiency of the new 7,000 square foot animal housing facility.

The service has procured modular housing units for the purpose of maintaining domestic (farm) animals. The units will be a valuable asset in the days ahead, allowing us to handle a variety of farm animals due to the decreased use of dogs and cats for biomedical research and training.

Other equipment purchased by the department include a fiberoptic laproscope and accessories for the study of luteal phase defects in the cynomolgous monkey model and cryolathe for use in studying keratorefractive surgery as a possible correction of refractive errors.

Work has begun on the final items of construction on Building 610. The installation of bumper guards for the corridors, the installation of a drain for the facility grounds and an extension of existing fencing will represent completion of the project.

The service will make use of its newly acquired personal computer for animal recordkeeping, collection and retrieval of data for regulatory agency reports and computer generated files.

The service has been notified that it has received full accreditation status by the American Association for the Accreditation of Laboratory Animal Care for the Fitzsimons Army Medical Center animal care facility.

#### Biochemistry Service

Studies of the medical significance of the many varied and apparently opposing functions of prostaglandins continues to require a sustained effort by the biochemistry laboratory. In one completed study in rats,  $^{131}\text{I}$ -induced hypothyroidism resulted in a reduced platelet count and a 30% decrease in platelet-generated thromboxane  $\text{A}_2$  ( $\text{TxA}_2$ ). Prostacyclin ( $\text{PGI}_2$ ) formation by aorta rings in hypothyroid rats changed little over the course of the study (23 wks), while  $\text{PGI}_2$  formation in euthyroid rats decreased by 40%.

Daily injection of 23 week old hypothyroid rats with thyroxine for 28 days caused a rapid increase in platelet count and a gradual reversal of prostaglandin synthesis abnormalities to values no different from age-matched euthyroid rats.

In other ongoing research, the absorption, distribution and elimination kinetics of atropine sulfate in sheep has been examined. This data is currently being fitted to an appropriate pharmacokinetic model through the use of a computer program at FDA. Other metabolic studies have been concerned with the hormonal regulation of angiotensin converting enzyme (ACE). In castrated male rats, levels of serum ACE were significantly reduced in comparison with sham-castrated animals. Treatment of castrated animals with estradiol further reduced levels of serum ACE. When testosterone was administered to castrated animals, serum ACE levels similar to those seen in sham-castrated animals were reestablished. In conjunction with the support of approved protocols, the biochemistry laboratory continues to meet specific needs of clinicians at FAMC by performing hundreds of specialized assays for such diverse entities as glycosylated hemoglobin ( $\text{A}_1\text{C}$ ), glucagon,  $\text{PGE}_2$ , antihistamines and toxic serum levels of methanol.

#### Cell Physiology Service

This service was created to support research on normal and disease state human tissue using in vitro and heterotransplantation model systems. Support of a major basal cell carcinoma (BCC) project is a result of this laboratory's novel success of growing basal cell carcinomas in athymic mice. This accomplishment resulted in definitive histologic research characterizing BCC growth. The research has been reported in three publications, four abstracts and/or concurrent presentations and two

publications being reviewed. Results of an off-shoot project using cultured keratinocytes has so far resulted in one publication for review and one currently being composed. Additionally, a project characterizing steroid production changes occurring in induced luteal phase defects in monkeys is being accomplished using short-term luteal cell culture techniques. The electron microscopy section has supported both tumor pedigree verification and the localization of immunoglobulins present in a myeloma.

#### Immunology Service

The EPICS V Flow Cytometry system has been upgraded by the addition of a direct high-speed data link (Ethernet) to an external computer-based data management system. This modification will permit a substantially higher throughput with the flow cytometer with concurrent data analysis at an independent work station. Current procedures utilizing flow cytometry include lymphocyte subtyping by two-color immunofluorescence, DNA ploidy analysis and T-cell activation analysis. One- and two-dimensional electrophoretic blotting procedures (Western and Southern Blots) have been developed in support of protocol research. An immunoenzymatic "dot" procedure (ELISA Dot Blot) has been also developed which reproducibly detects antigens/antibodies in amounts of 0.1 nanograms. Recently, these procedures have been utilized for the characterization of lymphocyte membrane receptors operative in antigen recognition and for the analysis of cross allergenicity of local pollen extracts.

#### Microbiology Service

The diagnostic mycobacteriology laboratory continued to achieve excellent scores on the quarterly CAP proficiency surveys during FY 85. Its record is now 13 perfect scores out of 14 surveys. During FY 85, a total of 2694 specimens were received for mycobacteriology processing (ave=225/mo.).

Considerable progress was made on several research protocols supported by the Microbiology Service resulting in 5 presentations at scientific meetings and one publication in a scientific journal. In addition, two manuscripts have been accepted for publication during FY 86 and three others have been submitted for publication.

### Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

### OMA

Civilian Personnel	535,273
Contracts	10,298
Supplies	285,232
Ceep Equipment	35,285
Travel	8,218

### OPA

MEDCASE	48,000
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PUBLICATIONS

## PUBLICATIONS

### DEPARTMENT OF MEDICINE

#### Allergy Service

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(C) Direct result of approved registered protocol.

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### Rheumatology Service

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Green, D. and Phillips, G.: Vaginal Prosthesis for Control of Vesicovaginal Fistulas. *Gyne Oncol*, in press.

Phillips, G. and Frye, L.: Carcinoma of the Cervix with Adenoid Cystic Component - Review of the Literature in a Case Report with Implications for Chemotherapeutic Treatment. *Gyne Oncol*, in press.

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Stoker, J.T. and Malczak, H.T.: A Study of Pulmonary Ligament Arteries. Chest 86:611, October 1984.

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#### DEPARTMENT OF NURSING

Dames, D.F.: Effects of Cimetidine and Glycopyrrolate in Combination, on Gastric pH in Adult Preoperative Patients Versus Diazepam. Completed at Walter Reed Army Medical Center During Phase II Army Anesthesia School for ANC Officers.

Wehner, Robert: Anesthesia for Oral Surgery. Publication AANA.

(C) Direct result of approved registered protocol.

## DEPARTMENT OF SURGERY

### Cardiothoracic Surgery Service

Effler, D.B., Pezzella, A.T. and Levy I.E.: Postinfarction Ventricular Aneurysmectomy. Am J Surg 149:793-796, 1985.

Fall, S.M. and Graeber, G.: Repair of Innominate Vein Rupture. Ann Thoracic Surg 38:302, 1984.

Huyke, E., Cohen, I., Fall, S.M. and Burton, S.: Granulomatous Endocarditis with Systemic Embolization in Behcet's Disease. Ann Int Med 102:791, 1985.

### General Surgery Service

Adams, C.W., McPhail, J.F.III. and Clark, J.R. Hodgkins Disease of the Breast. Pending publication in Contemporary Surgery (accepted June 1985) and pending publication in CANCER (accepted January 1985).

### Orthopedic Service

Houseworth, S.W., Kieffer, D.A., Mauro, V.J. and Mellon, B.A.: The Intercondylar Notch in Acute Tears of the Anterior Cruciate Ligament: A Computer Graphics Study. Accepted for publication in Orthopaedic Transactions. (C)

Lisecki, E.J.: Aspiration of Prosthetic Hips Under Ultrasonic Control. J Hand Surg, July-August 1985.

Loth, T.S.: Treatment Methods for Extravasations of Chemotherapeutic Agents: A Comparative Study. Accepted for publication in Journal of Hand Surgery. (C)

Wilkerson, R.D., Curl, W.W., Opal, S.M. and Taylor, D.C.: Nocardia Ateroides Sepsis of the Knee. Clinical Orthopaedics & Related Research, 197:206-208, July-August 1985.

Wilkerson, R.D., Coville, F.V. and Paull, W.: Necrotizing Fasciitis - Review of the Literature and Case Report. Accepted for publication in Clinical Orthopaedics and Related Research.

### Otolaryngology Service

Blakeslee, D.B., Becker, G.D., Simpson, G.T., Patten, D.H. and Sprengelmeyer, J.: Lymphoscintigraphy of the Neck. Otolaryngology Head Neck Surgery 93:361, June 1985.

(C) Direct result of approved registered protocol.

### Urology Service

Shipton, W.E. and Wilson, T.M.: Urolithiasis in Pregnancy. Kimbrough Urological Proceedings, 1984.

Vaught, W.W. and Fitzsimons Staff: Diagnosis of Prostatic Abscess Using CT Scan. Kimbrough Urological Proceedings, 1984.

Vordermark, J.S.: The Acute Scrotum: Adjunctive Diagnostic Techniques. Emergency Med Annual: 1984, Wolcott and Rund. Editors: Appleton-Century-Crofts, New York.

Vordermark, J.S.: Acute Epididymitis: Experience with 123 Cases. Military Medicine 150:27-30, 1985.

Vordermark, J.S. (co-author): Approaches to Block Dissection of the Inguinal Lymph Nodes. In press - Brit J Plas Surg.

Vordermark, J.S. (co-author): Transureteroureterostomy: A Review of its Use in Modern Pediatric Urology. In press - Brit J Urol.

Vordermark, J.S.: The Acute Scrotum in Childhood: A Review. In press - World J Urol.

Wilson, T.M.: Retroperitoneal Fibrosis in Association with Abdominal Aortic Aneurysm. Kimbrough Urological Proceedings, 1984.

Wolthuis, J.S. and Fitzsimons Staff: Extradural Metastasis of Prostate Carcinoma. Kimbrough Urological Proceedings, 1984.

PRESENTATIONS

## PRESENTATIONS

### DEPARTMENT OF MEDICINE

#### Allergy Service

Bowen, R.E. and Nelson, H.S.: A Double-Blind Crossover Study of Long-Term Inhaled Atropine Methonitrate. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985. (C)

Bowen R.E. and Nelson, H.S.: A Double-Blind Crossover Study of Long-Term Inhaled Atropine Methonitrate. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985. (C)

Kray, K.T., Vandewalker, M.L., Weber, R.W. and Nelson, H.S.: Double-Blind Study of Long-Term Oral Terbutaline: Efficacy and Side Effects. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985. (C)

Kray, K.T.: Double-blind Study of Long-Term Oral Terbutaline: Efficacy and Side Effects. Presented: 41st Annual Meeting, The American Academy of Allergy and Immunology, New York, NY, 16-20 March 1985. (C)

Miller, B.T.: Double-Blind Study of Immunotherapy with Polymerized Grass. Presented: 37th Annual Fitzsimons Army Medical Symposium, 23-25 January 1985. (C)

Miller, B.T.: Comparison of Standardized, Quantitative Skin Test Assay and RAST Inhibition for Assessment of Extract Potency. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985. (C)

Miller, B.T., Brown, J.S., Moyer, D.B., Weber, R.W. and Nelson, H.S.: Double-Blind, Controlled Trial of Polymerized Grass Pollens in the Treatment of Seasonal Allergic Rhinitis. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985. (C)

Miller, B.T., Ledoux, R.A., Brown, J.S. and Nelson, H.S.: Comparison of Standardized Quantitative Skin Test Assay and RAST Inhibition for Assessment of Extract Potency. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985. (C)

Moyer, D.B.: Persistence of Imported House Dust Mites in Colorado. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985. (C)

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(C) Direct result of approved registered protocol.

Nelson, H.S.: Beta Adrenergic Agonists: Clinical Usefulness and Development of Tolerance. Presented: Symposium on Allergy-Immunology, Ann Arbor, Michigan, 26 October 1984.

Nelson, H.S.: Diagnostic Tests in Allergy. Presented: Annual Meeting of American Osteopathic College of Allergy-Immunology, Las Vegas, Nevada, 5 November 1984.

Nelson, H.S.: Immunotherapy Update. Presented: The 11th Annual Allergy Symposium of the Southern California Region, Kaiser Permanente, Orange, California, 15 December 1984.

Nelson, H.S.: Beta Adrenergic Agonists: Clinical Usefulness and Development of Subsensitivity. Presented: Keystone Summit 1985 on Allergy-Immunology, Pulmonary and ENT, Keystone, Colorado, 14 January 1985.

Nelson, H.S.: Bela Schick Memorial Lectures "Atopic Diseases". Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985.

Tipton, W.R.: Functional Shelf Life of Methacholine and Atropine Methylnitrate Solutions. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985. (C)

Vandewalker, M.L.: Double-Blind Crossover Study of Inhaled Terbutaline in Asthmatics on Optimal Theophylline Therapy. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985. (C)

Vandewalker, M.L., Kray, K.T., Weber, R.W. and Nelson, H.S.: Double-Blind, Crossover Study of Long-Term Inhaled Terbutaline. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985. (C)

Vaughan, T.R.: Comparison of PEFR and FEV-1 in Patients with Varying Degrees of Airway Obstruction. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985.

Vaughan, T.R., Weber, R.W., Tipton, W.R. and Nelson, H.S.: Comparison of PEFR and FEV-1 in Patients with Varying Degrees of Airway Obstruction. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985.

Vaughan, T.R.: Plasma Histamine Elevation During Blind Food Challenges Which Provoke Migraine. Presented: Third Annual Aspen Allergy Conference, Aspen, CO, 24-27 July 1985.

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(C) Direct result of approved registered protocol.

Weber, R.W.: Risk Assessment for Recurrent Adverse Reaction to Local Anesthetics. Presented: 37th Annual Fitzsimons Symposium, 23-25 January 1985.

Weber, R.W.: Evaluation of Prior Adverse Reactions to Local Anesthetics by Skin Tests and Provocative Challenge. Presented: 41st Annual Congress American College of Allergists, Bal Harbour, FL, 2-6 February 1985.

Weber, R.W.: Mechanisms of Adverse Reactions to Local Anesthetics. Presented: Third Annual Aspen Allergy Conference, Aspen, CO, 24-27 July 1985.

#### Cardiology Service

Bowden, W.D.: Two Dimensional Echocardiographic Evaluation of Exercise Induced Wall Motion Abnormalities: Detection of Coronary Artery Disease. Presented: Army Association of Cardiology meeting, William Beaumont Army Medical Center, El Paso, Texas, May 1985. (C)

Raible, S.J.: Permanent Cardiac Pacing. Presented: Army Association of Cardiology Meeting, William Beaumont Army Medical Center, El Paso, TX, May 1985.

Svinarich, J.T.: Is Beta-Adrenergic Blockade Contraindicated in Wolff-Parkinson-White Patients Prone to Atrial Fibrillation?. Presented: American Heart Association, 57th Scientific Sessions, Miami Beach, Florida, November 1984.

Thomas, H.M.Jr.: An Analysis of Cardiologic and Cardiac Surgical Interventions Generated in 1984 at Fitzsimons Army Medical Center. Presented: Army Association of Cardiology meeting, William Beaumont Army Medical Center, El Paso, TX, May 1985.

#### Endocrinology Service

Asp, A., Opal, S. and Cannady, P.: Efficacy of Infection Control Measures in Aspergillosis Outbreak. Presented: Third Annual American College of Physicians Associates Meeting, Denver, CO, March 1985. (C)

Sjoberg, R.J., Kidd, G.S., Swanson, E., O'Barr, T., Wetherill, S., Corby, D. and Hofeldt, F.D.: Thromboxane and Prostacyclin Generation in Hypothyroidism. Presented: Eastern Section, American Federation for Clinical Research, Philadelphia, PA, October 1984. (C)

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(C) Direct result of approved registered protocol.

Sjoberg, R., Swanson, E., O'Barr, T., Walden, T. and Kidd, G.: Influences of Methylprednisolone and Desoxycorticosterone with Salt-Loading on the Ability of Arterial and Renal Tissue to Produce Prostaglandins. Presented: 67th Annual Meeting of The Endocrine Society, Baltimore, MD, June 1985. (C)

Verma, P.S., Chadwick, E.W. and Georgitis, W.J.: Effects of Castration and Sex Steroid Treatment on Serum Angiotensin Converting Enzyme Activity. Presented: 67th Annual Meeting of The Endocrine Society, Baltimore, MD, June 1985. (C)

#### Nephrology Service

Copley, J.B. and Hasbargen, J.A.: Primary Hematuria; A Prospective Evaluation. Presented: American Society of Nephrology Conference, December 1984. (C)

#### Pulmonary Disease Service

Perry, M.E.: A Graphical Analysis of Body Plethysmography. Presented: Carl Temple Pulmonary Symposium, San Francisco, CA, October 1984.

Pluss, J.L.: Pulmonary Sporotrichosis: Review of Treatment and Outcome. Presented: Carl Temple Pulmonary Symposium, San Francisco, CA, October 1984.

Witte, M.C.: Incidence of Fever and Bacteremia Following Transbronchial Needle Aspiration. Presented: Carl Temple Pulmonary Symposium, San Francisco, CA, October 1984. (C)

Wolfe, G.K.: CO<sub>2</sub> Retention During PEEP with High Frequency Jet Ventilation. Presented: Carl Temple Pulmonary Symposium, San Francisco, CA, October 1984.

#### Rheumatology Service

West, S.G. and Andersen, P.A.: the Prevalence of Sjogren's Syndrome in Patients with SLE who have Anti-SS-A Antibodies. Presented: 49th American Rheumatism Association Meeting, Anaheim, CA, June 1985.

#### DEPARTMENT OF CLINICAL INVESTIGATION

Georgitis, W.J., Walden, T.L., Kidd, G.S. and Verma, P.S.: Effects of Castration and Testosterone on Serum Angiotensin Converting Enzyme Activity. Presented: 2nd Annual Army Regional American College of Physicians, San Francisco, CA, October 1985. (C)

(C) Direct result of approved registered protocol.

Sjoberg, R., Swanson, E., O'Barr, T., Walden, T. and Kidd, G.: Influences of Methylprednisolone and Eoxycortosterone with Salt-Loading on the Ability of Arterial and Renal Tissue to Produce Prostaglandins. Presented: 67th Annual Meeting The Endocrine Society, Baltimore, MD, 1985. (C)

Verma, P.S., Chadwick, E.W. and Georgitis, W.J.: Effects of Castration and Sex Steroid Treatment on Serum Angiotensin Converting Enzyme Activity. Presented: 67th Annual Meeting of Endocrine Society, Baltimore, MD, 1985. (C)

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P.G. and Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrous Acid Extraction Technique. Presented: Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985. (C)

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P.G. and Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrous Acid Extraction Technique. Presented: Fifth Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985.

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P.G. and Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrous Acid Extraction Technique. Presented: Fourteenth Aspen Conference on Pediatric Research, Aspen, CO, July 1985. (C)

Opel, S.M., Cannady, P.B., Asp, A.A. and Morse, P.L.: The Epidemiology of Nosocomial Aspergillosis Associated with Hospital Construction. Presented: 85th Annual Meeting of The American Society for Microbiology, Las Vegas, NV, March 1985. (C)

Paine, D.D., W therill, S.R. III and Engelkirk, P.G.: In Vitro Cytotoxic Effects of Human Peripheral Blood Components on Giardia lamblia Trophozoites as Measured by Release of <sup>111</sup>Indium. Presented: 85th Annual Meeting of The American Society for Microbiology, Las Vegas, NV, March 1985. (C)

#### DEPARTMENT OF NURSING

Wehner, R.: Airway Mangement, Muscle Relaxants in Trauma. Presented: Savannah, GA, 1985.

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(C) Direct result of approved registered protocol.

DEPARTMENT OF OB-GYN

Sarno, A. and Potter, J.: Simultaneous Ectopic & I-trauterine Pregnancy: A Case Report and Review of the Literature. Presented: AFD/ACOG, Atlanta, Georgia, October 1984.

Williams, V., Phillips, G. and Brady, W.: Dystocia Secondary to Congenital Primitive Mesenchymal Tumor. Presented: AFD/ACOG, Atlanta, Georgia, October 1984.

DEPARTMENT OF PEDIATRICS

Hurst, D.L.: The Use of Imipramine as an Anticonvulsant for Minor Motor Seizures. Presented: Child Neurology Society, Phoenix, Arizona, October 11-13, 1984.

Hurst, D.L.: Carbamazepine Induced Absence and Minor Motor Seizures. Presented: 37th Annual Meeting of the American Academy of Neurology, Dallas, TX, April 28-May 4, 1985.

Merenstein, G.B.: Management of Hyperbilirubinemia. Presented: Pediatrics in Practice, 75th Anniversary Meeting Denver Children's Hospital, Denver, CO, 15 February 1985.

Murphy, M.G. and Peck, C.C.: Revisions of Gentamicin Therapy with a Bayesian Computer Program. Presented: Triservices Pediatric Meeting, Norfolk, VA, March 1985.

Murphy, M.G., Pierce, J.R., Berkenbaugh, J.T. and Merenstein, G.B.: Nalozone Therapy of Streptococcal Sepsis in a Suckling Rat Model. Presented: COMPRA, Aspen, CO, July 1985. (C)

Nelson, S.N., Mosijczuk, A.D., Grahma, L. and Hess, J.: Problems in Screening for Latent Iron Deficiency. Presented: Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985. (C)

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P.G. and Morse, P.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrous Acid Extraction Technique. Presented: Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; 5th Annual Conference on Military Perinatal Research, Aspen, CO, 15 July 1985; 14th Aspen Conference on Perinatal Research, Aspen, CO, 18 July 1985. (C)

Sanders, J.M.: Adolescent Substance Abuse. Presented: Annual Meeting for American Academy of Pediatrics, Chicago, IL, September 1984.

(C) Direct result of approved registered protocol.

Sanders, J.M.: Approach to the Adolescent Patient. Adolescent Substance Abuse. Presented: Annual Meeting of the Texas Pediatric Society, Dallas, TX, September 1984.

Sanders, J.M.: Approach to the Adolescent Patient. Presented: Pediatric Grand Rounds, University of Kansas School of Medicine, Wichita, Kansas, October 1984.

Sanders, J.M.: Normal Adolescence: Fact or Fiction, Talking to the Adolescent Patient in the Physicians Office: The Hidden Agenda, Adolescent Suicide. Presented: Lectures at East Tennessee State University School of Medicine, Johnson City, Tennessee, February 1985.

Sanders, J.M.: Adolescent Crises in the Emergency Room. Presented: 20th Annual Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985.

Sanders, J.M.: Adolescent Substance Abuse. Presented: Spring Meeting, American Academy of Pediatrics, Atlanta, Georgia, April 1985.

Sanders, J.M.: Adolescent Substance Abuse, Approach to the Adolescent Patient. Presented: Visiting Professor, Texas A&M School of Medicine and Scott & White Clinic, Temple, Texas, August 1985.

Sanders, J.M.: Current Trends in Adolescent Substance Abuse. Presented: Blackford Memorial Lecture, Dennison, Texas, September 1985

#### DEPARTMENT OF SURGERY

##### Cardiothoracic Surgery Service

F-11, S.M.: Use of Centrifugal Pump as a Ventricular Assist Device. Presented: Regional Meeting, American Society for Extracorporeal Circulation, Silver Creek, Colorado - 21 February 1985.

Fall, S.M.: Use of Lidocaine to Prevent Ventricular Fibrillation Following Aortic Cross-Clamping. Presented: 34th Annual Scientific Meeting, American College of Cardiology, Anaheim, California - 12 March 1985.

Pezzella, A.T.: Noncardiac Uses of Cardiopulmonary Bypass. Presented: Regional Meeting, American Society of Extracorporeal Circulation, Silver Creek, Colorado - 21 February 1985.

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(C) Direct result of approved registered protocol.

#### General Surgery Service

Adams, Carl W., Clark, J.R., McPhail, J. F. III and Lisanti, M.J.: Presented: 1985 Gary P. Wratten Surgical Symposium, Brooke Army Medical Center, Ft. Sam Houston, TX 8-10 April 1985.

Conarro, P.A. and Clark, J.R.: Complications of Operation for Morbid Obesity at Fitzsimons Army Medical Center. Presented: 1985 Gary P. Wratten Surgical Symposium, Brooke Army Medical Center, Ft. Sam Houston, TX 8-10 April 1985.

Laskin, J.A. and Clark, J.R.: Disseminated Aspergillosis in Intensive Care Units. Presented: 1985 Gary P. Wratten Surgical Symposium, Brooke Army Medical Center, Ft. Sam Houston, TX 8-10 April 1985.

Mallory, P., McPhail, J.F. III. and Clark, J.R.: Adenocarcinoma of the Sigmoid Colon Presenting as an Incarcerated Inguinal Hernia. Presented: 1985 Gary P. Wratten Surgical Symposium, Brooke Army Medical Center, Ft. Sam Houston, TX 8-10 April 1985.

#### Orthopedic Service

Coville, F.V.: Neufeld Traction. Presented: Symposium on Spinal, Upper and Lower Extremity Orthotics, Aurora, CO, May 1985.

Flood, S.: Ankle Fractures. Presented: St. Anthony's Hospital Orthopaedic Symposium for Nurses, Denver, CO, May 1985.

Flood, S., et.al.: Ewing's Sarcoma. Presented: Denver Children's Hospital Annual Pediatric Orthopedic Symposium, Denver, CO, April 1985.

Frushour, S.J.: History of Brace Treatment of Scoliosis. Presented: 13th Annual Symposium of Children's Orthopedics, Aurora, CO, February 1985.

Hahn, D.B.: Treatment of the Serpentine Foot. Presented: 13th Annual Symposium of Children's Orthopedics, Aurora, CO, February 1985.

Houseworth, S.W.: Acute Hemarthrosis of the Knee in a Young Athletic Population. Presented: Society of Military Orthopaedic Surgeons Annual Meeting, Oakland, CA, December 1984.

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(C) Direct result of approved registered protocol.

Houseworth, S.W.: The Intercondylar Notch in Acute Tears of the Anterior Cruciate Ligament: A Computer Graphics Study. Presented: 1) Society of Military Orthopaedic Surgeons, Oakland, CA, December 1984; 2) American Orthopaedic Society of Sports Medicine Annual Meeting, Nashville, TN, July 1985; 3) Western Orthopaedic Society Annual Meeting, Houston, TX, October 1985. (C)

Jones, D.E.: Congenital Hand Deformities. Presented: 13th Annual Symposium of Children's Orthopedics, Aurora, CO, February 1985.

Jones, D.E.: Orthotics for the Rheumatoid Hand. Presented: Symposium on Spinal, Upper and Lower Extremity Orthotics, Aurora, CO, May 1985.

Lisecki, E.: Anterior Cruciate Ligament Deficiency in Children. Presented: Children's Orthopedic Symposium, Denver, CO, April 1985.

Lisescki, E.: Closed Ambulatory Treatment for Peritrochanteric Fractures. Presented: Western Orthopaedic Society Barnard Seminar, Denver, CO, December 1984.

Loth, T.S.: Treatment Methods for Extravasations of Chemotherapeutic Agents: A Comparative Study. Presented: 1) Society of Military Orthopaedic Surgeons Annual Meeting, Oakland, CA, November 1984, (Winner, Norman T. Kirk Award); 2) Mid Central States Orthopaedic Society, Lake of the Ozarks, MO, June 1985, (Winner, Resident's Award). (C)

Morrissey, J.B.: Distal Humerus Fractures in Children. Presented: Barnard Seminar, Denver, CO, November 1984.

Morrissey, J.B.: The Use and Complications of External Fixation. Presented: St. Anthony's Orthopaedic Seminar, Denver, CO, May 1985.

Morrissey, J.B.: Scoliosis, Legg-Perthes Disease, and Osteomyelitis. Presented: Pediatric Nurse Course, Denver, CO, September 1985.

Ozaki, J.K.: Congenital Dislocation of the Knee. Presented: 13th Annual Symposium of Children's Orthopedics, Aurora, CO, February 1985.

Wilkinson, R.D.: Shoulder Dislocations. Presented: St. Anthony's Hospital Orthopaedic Symposium for Nurses, Denver, CO, May 1985.

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(C) Direct result of approved registered protocol.

Wilkerson, R.D., et.al.: Necrotizing Fasciitis - Review of the Literature and Case Report. Presented: Rocky Mountain Chapter of Western Orthopaedic Society Barnard Seminar, Denver, CO, December 1984.

#### Otolaryngology Service

Lowry-Romero, F.: Alternative Communication Systems - Show and Tell. Presented: Colorado Speech-Language-Hearing Association, Colorado Springs, CO, April 1985.

Lowry-Romero, F.: Relaxation Therapy - 180° From Traditional Therapy. Presented: Colorado Speech-Language-Hearing Association, Colorado Springs, CO, April 1985.

Lowry-Romero, F.: Care and Treatment of the Voice - Voice Evaluation and Background Information. Presented: Fourteenth Symposium - Care of the Professional Voice, Denver, CO, June 1985.

Yuko, R.T. and Blakeslee, D.B.: Recurrent Cholesteatoma of the Infratemporal Fossa. Presented: XIII World Congress of Otorhinolaryngology, Miami Beach, Florida, May 1985.

#### Urology Service

Fauver, H.E., Jr. (co-author): Endometrial Cancer of the Postate. Presented: Poster Session. 79th Annual AUA Meeting, 1984.

Fauver, H.E., Jr. (co-author): Unilateral Absence of the Vas. Presented: Poster Session. South Central Section Meeting of AUA, 1984.

Fauver, H.E., Jr. (co-author): Paratesticular Tumors. Presented: Poster Session. South Central Section Meetings of AUA, 1984.

Raife, M.J. (co-author): Neurofibromatosis. Presented: Poster Session. South Central Section Meeting of AUA, 1984.

Shipton, W.E. and Wilson, T.M. & Fitzsimons Staff: Urolithiasis in Pregnancy. Presented: Kimbrough Urological Proceedings, 1984.

Vaught, W.W. and Fitzsimons Staff: Diagnosis of Prostatic Abscess Using CT Scan. Presented: Kimbrough Urological Proceedings, 1984.

(C) Direct result of approved registered protocol.

Wilson, T.M.: Retroperitoneal Fibrosis in Association with Abdominal Aortic Aneurysm. Presented: Kimbrough Urological Proceedings, 1984.

Wolthuis, J.S. and Fitzsimons Staff: Extradural Metastasis of Prostate Carcinoma. Presented: Kimbrough Urological Proceedings, 1984.

DEPARTMENT OF RADIOLOGY

Hopper, K.D., Moser, R., Haseman, D., Sweet, D. and Kransdorf, M.: Osteosarcomatosis. Presented: Radiological Society of North America, Washington, D.C., November 1984.

Hopper, K.D. and Sherman, J.: The Variable Fusion of the Lateroconal Fascia and It's Affect on the Retroperitoneal Colon. Presented: Radiological Society of North America, Washington, D.C., November 1984.

Jackson, J.H., Blue, P.W. and Ghaed, N.: Glomerular Filtration Rate Determined in Conjunction with Routine Renal Scan. Presented: Western Regional Society of Nuclear Medicine, Monterey, CA, October 1984.

(C) Direct result of approved registered protocol.

## EXPLANATION OF ANNUAL PROGRESS REPORT DETAIL SHEETS

- (1) DATE: Fiscal Year ending date.
- (2) PROTOCOL NO: FAMC Work Unit Number of the study.
- (3) STATUS: Indicates if the study if Ongoing, Completed, or Terminated.
- (4) TITLE: Project title of the study.
- (5) START DATE: The date the study started.
- (6) ESTIMATED COMPLETION DATE: The projected completion date of the study.
- (7) PRINCIPAL INVESTIGATOR(s): List of all Principal Investigator(s) involved in the study.
- (8) FACILITY: Fitzsimons Army Medical Center.
- (9) DEPARTMENT/SECTION: Department or Service the protocol originated from.
- (10) ASSOCIATE INVESTIGATOR(s): List of all Associate Investigator(s) involved in the study.
- (11) KEY WORDS: Key words pertaining to the particular area of research involved in the study.
- (12) ACCUMULATIVE MEDCASE COST: See Unit Summary Sheet - Funding.
- (14) PERIODIC REVIEW RESULTS: Date of the continuing review by the Institutional Review Committee.
- (15) STUDY OBJECTIVE: A summary of objectives to be accomplished during the study.
- (16) TECHNICAL APPROACH: A brief summary of the technical approach to be taken during the study.
- (17) PROGRESS: A summary of prior and current progress since inception of the study.

The Continuation Sheets are used as extensions for (1) - (17) and as an accumulative listing for Publications and Presentations that are a direct result from the study.

The Detail Sheets were submitted in final form by the Principal Investigators and have not been edited.

DETAIL SUMMARY SHEETS

MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 74/110 (3) Status: Ongoing	
(4) Title: REACTIVE HYPOGLYCEMIA: AN ANALYSIS OF GLUCOSE-INSULIN-GLUCAGON INTERRELATIONSHIPS AND COUNTER HORMONAL REGULATORY FACTORS	
(5) Start Date: FY71	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Michael Bornemann, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Fred D. Hofeldt, M.D. T.P. O'Barr, Ph.D., DAC Annelie Shackelford, MT, DAC Gerald S. Kidd, LTC, MC
(11) Key Words: reactive hypoglycemia glucose intolerance counter-regulatory hormones	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: 9/84 b. Review Results: Ongoing	
c. Number of Subjects Enrolled During Reporting Period: 7	
d. Total Number of Subjects Enrolled to Date: 391	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.	

(15) Study Objective:

The objectives of the hypoglycemic study is to continue to investigate in our clinic population the glucose-insulin-glucagon and prolactin interrelationships and the response of counter-regulatory hormones to hypoglycemic stress. This project is a continuation of the previous project initiated in 1969 at the University of California Medical Center, Moffatt Hospital, San Francisco, CA.

(16) Technical Approach:

The clinical research protocol involves evaluation of control subjects and hypoglycemic patients to assess the interrelationships of beta cell and alpha cell responsiveness to oral and intravenous glucose administration. Based upon findings in controls and patients with disease states, a classification system has been proposed. The data have allowed for an understanding of the basic pathophysiology of reactive hypoglycemia disorders. The clinical studies are being conducted in the Department of Medicine, Endocrine Clinic, with the assistance of an assigned GS-5 Medical Technician to perform blood sampling and to assist during the testing. During the glucose tolerance test, the patient has an indwelling catheter for frequent sampling of blood glucose, and is continually monitored by a cardiac monitor system and blood sampling. After glucose administration, blood insulins, glucagons, growth hormones, prolactins and cortisols

## (16) Technical Approach - continued:

are sampled and values are determined by a sensitive radioimmunoassay. Blood glucoses are assessed by the Ames Reflectance Meter immediately after sampling. The procedure is designed to provide a minimum of patient inconvenience in the performance of these well standardized procedures. Many normal individuals experience a low blood sugar state sometime after glucose administration, the significance of a low blood glucose state is observed by recording appropriate adrenergic symptoms at the nadir of the glucose and determining if there is a counter hormonal responsiveness to defend the stress of a low blood glucose state. This approach allows strict definition of bona fide reactive hypoglycemia, and clearly distinguishes it from the benign low blood glucose states.

## (17) Progress:

This study continues to be an active endocrine protocol with the recruitment of new patients for evaluation and study. Several publications elucidating the unusual features of this disorder have resulted from this study in the past. During the last year computer analysis of the data, which was accomplished the previous year, has resulted in elimination of duplicate cases and incomplete cases. Efforts are now being made to organize the data in preparation for commencing several written reports on hypoglycemia in general, and some specific aspects which have been studied in the present ongoing protocol. No publications have arisen in the last fiscal year.

## Presentations:

- (1) Hofeldt, F.D.: Reactive Hypoglycemia: Update 1980. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 16 January 1980.
- (2) Sanders, L.R.: Reactive Hypoglycemia. Presented: Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 13 March 1979.
- (3) Sanders, L.R.: Reactive Hypoglycemia. Presented: Medical Grand Rounds, Denver General Hospital, Denver, CO, 15 March 1979.
- (4) Sanders, L.R.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, 11 April 1979.
- (5) Hofeldt, F.D.: Hypoglycemia. Grand Rounds, Delgado Amphitheater, Tulane Medical School Charity Hospital, New Orleans, LA, 28 April 1982.
- (6) Hofeldt, F.D., and Scarlett, J.A.: Reactive Hypoglycemia. Presented: Endocrine Grand Rounds, University of Colorado Health Sciences Center, Denver, CO, March 1982.

SERVICE EndocrineDEPARTMENT Medicine

- (1) Abrams, R., Hofeldt, F.D., Adler, R., O'Barr, T.P., and Morse, P.: Late Reactive Hypoglycemia in Hypothyroidism.
- (2) Hofeldt, F.D.: Transitional Low Blood Glucose States. Rocky Mountain Medical Journal 76:30, 1979.
- (3) McCowen, K.D., Adler, R.A., O'Barr, T.P., and Hofeldt, F.D.: Clinical Implications of Flat Oral Glucose Tolerance Test. Military Medicine 144:177, 1979.
- (4) Charles, M.A., Hofeldt, F.D., Dodson, L.E., Shackelford, A., Waldeck, N., Bunker, D., Coggins, J.T., and Eichner, H.: Comparison of Glucose Tolerance Tests and Mixed Meals in Patients With Idiopathic Reactive Hypoglycemia: Absence of Hypoglycemia After Mixed Meals. Diabetes 30:465, 1981.
- (5) Sanders, L.R., Hofeldt, F.D., Kirk, M., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072, 1982.
- (6) Crapo, P.A., Scarlett, J.A., Kolterman, O., Sanders, L., Hofeldt, F.D., and Olefsky, J.: The Effects of Oral Fructose, Sucrose and Glucose in Subjects With Reactive Hypoglycemia. Diabetes Care 5:512, 1982.
- (7) Sanders, L.R., Hofeldt, F.D., Kirk, M.C., and Levin, J.: Refined Carbohydrate as a Contributing Factor in Reactive Hypoglycemia. Southern Medical Journal 75:1072-1075, 1982.

# DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &  
HSPA-I Ltr,  
8 July 1982

(1) Date: FY21 Sept 83) Protocol WU Nr.: 78/114 (3) Status: Completed  
(4) Title: In vitro effect of minoxidil on collagen production by normal and scleroderma fibroblasts. Previously titled: The use of minoxidil in treating progressive systemic scleroderma.

(5) Start Date: Jan 1979 (6) Est Compl Date: Jan 1985  
(7) Principal Investigator: James E. Fitzpatrick MD  
Major, MC (8) Facility: FAMC

(9) Dept/Svc: DOM/Dermatology (10) Assoc Investigators:  
(11) Key Words: scleroderma, minoxidil  
fibroblasts, collagen Thomas P. O'Barr PhD, DAC  
Ellen Swanson MS, DAC  
Don Mercill, DAC

(12) Accumulate MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of subjects enrolled during reporting period: N/A  
d. Total number of subjects enrolled to date: N/A  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: To determine if minoxidil inhibits the in-vitro production of collagen by normal and scleroderma fibroblasts.

(16) Technical Approach: Fibroblast cell lines have been established from human dermis obtained from normal and scleroderma patients. The fibroblasts are then incubated in the presence of various concentrations of minoxidil. The production of collagen was measured by the uptake of radioactive proline.

The in-vivo portion of the protocol was completed as of 30 September 1982.

The in-vitro portion of the protocol was completed 1 Jan 1983. Analysis of the data failed to demonstrate significant evidence that minoxidil has any effect on the production of collagen by normal or scleroderma fibroblasts.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/123 (3) Status: Completed	
(4) Title: A Comparison of the Zimmerer and Dubois Techniques of Airway Resistance Measurements by Body Plethysmography	
(5) Start Date: 1979	(6) Est Compl Date: 1985
(7) Principal Investigator: Michael Perry, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators: Robert W. Zimmerer, Ph.D. Robert J. Browning, B.S., DAC
(11) Key Words: Alveolar pressure Airway resistance Body plethysmography	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: 0	
d. Total Number of Subjects Enrolled to Date: 7	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A	

(15) Study Objective: To compare a clinically untried measurement of airway resistance with a standard technique.

(16) Technical Approach: Forced expiratory maneuvers are performed with the subject seated in a constant volume body plethysmograph, while plethysmograph pressure and airflow are monitored with a DEC computer. With this information and the previously determined FRC of the patient, alveolar pressure is calculated throughout the expiratory maneuver. Pressure/flow relationships are then related to the patient's maximal expiratory flow volume loop.

(17) Progress: This protocol has been inactive during the past FY due to extensive changes and modifications of our equipment. Request this protocol be completed until such time a new modification of the study can be written.

SERVICE PulmonaryDEPARTMENT Medicine

- 1). Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography (Abstract) Symposium on Computers in Critical Care in Pulmonary Medicine, Page 47, June 1980.
- 2). Perry, M.E., Zimmerer, R.W., Nelson, R.A., Browning, R.J., Non-Invasive Determination of Alveolar Pressure-Flow Relationship (Abstract) American Review of Respiratory Disease, Volume 121, Page 389, April 1980.
- 3). Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography (Abstract) AAMI 15th Annual Meeting, Page 246, April 1980.
- 4). Perry, M.E., Zimmerer, R.W., Browning, R.J.: "Non-Invasive Alveolar Pressure/Flow Pattern Determinations by computerized Plethysmography", Computers in Critical Care and Pulmonary Medicine, Volume 2, PP 75-77 Plenum Press, 1982.

## PRESENTATIONS:

- 1) Perry, M.E., Zimmerer, R.W., Browning, R.J.: Non-Invasive Alveolar Pressure/Flow Pattern Determination by Computerized Plethysmography, presented at the Annual Computers in Critical Care and Pulmonary Medicine, Lund, Sweden, June 3-6, 1980.
- 2) Zimmerer, R.W., Perry, M.E., Browning, R.J.: Expiratory Pressure/Flow Assessment by Plethysmography, presented at the AAMI 15th Annual Meeting San Francisco, April 13-17, 1980.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/124 (3) Status: Completed  
 (4) Title: A Self-consistent Method of Single-Breath DLCO Measurement

(5) Start Date: 1978	(6) Est Compl Date: 1985
(7) Principal Investigator: Michael E. Perry, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators:
(11) Key Words: single breath diffusion alveolar gas breathing patterns	Neal B. Kindig, Ph.D. Robert J. Browning, B.S.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 0  
 d. Total Number of Subjects Enrolled to Date: 5  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To experimentally confirm a proposed new method of DLCO measurement.

(16) Technical Approach: Data will be sampled during the single breath DLCO determination at various breath-holding times at various exhaled lung volumes. Data will be analyzed online by computer which will correct for volume averaging and effective breath-holding time. If the theoretical approach as outlined in the original protocol is self-consistent, the calculated diffusion capacity should remain constant regardless of breathing pattern of gas collection timing.

(17) Progress: This protocol remains inactive this FY due to other priorities. Request completion of this protocol.

SERVICE PulmonaryDEPARTMENT Medicine

- 1). Zimmerer, R.W.: Simulated Diffusion Testing. Presented: 32nd Annual Pulmonary Symposium, FAMC, Aurora, CO, September 1979.
- 2). Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Presented at the Nineteenth International Instrument Society of America Biomedical Sciences Instrumentation Symposium, Denver, CO, April, 1982.
- 3). Kindig, N.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging". Presented at the Annual FASEB Meeting, New Orleans, April, 1982.
- 4). Kindig, N.B., "Single Breath DLCO: Improved Time and Volume Measurement". Presented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.
- 5). Perry, M.E., "Mechanism of Carbon Monoxide Effect on Oxyhemoglobin Dissociation". Presented at the Annual Carl W. Tempel Pulmonary Symposium, Denver, CO, Jan, 1982.

## PUBLICATIONS:

- 1). Kindig, N.B., Hazlett, D.R., Filley, G.F.: "Timing and Volume Averaging in Single Breath DLCO Measurement". The Physiologist, 21:64, 1978
- 2). Browning, R.J., Kindig, N.B., Perry, M.E., "Computer Control Aspects of a Single Breath DLCO Station." Biomedical Sciences Instrumentation, Volume 18, April, 1982.
- 3). Kindig, N.B., Perry, M.E., Browning, R.J., "Single Breath DLCO: Inspiratory Timing and Volume Averaging (ABS) Federation Proceedings, Volume 41, Mar, 1982.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 79/105 (3) Status: Ongoing  
 (4) Title: Breathing Pattern Effects on Steady-State DLCO Measurement

(5) Start Date: November 1979	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Michael E. Perry, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators: Neal B. Kindig, PH.D.
(11) Key Words:  Steady State DLCO Breathing Pattern	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 0  
 d. Total Number of Subjects Enrolled to Date: 0  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To experimentally confirm theoretically determined corrections for breathing pattern during steady-state diffusion studies.

(16) Technical Approach: Breathing Patterns with variations in inspiratory and expiratory breath-holds will be performed while the subject undergoes standard steady state diffusion measurement. If our approach is correct, mathematical corrections for breathing pattern will result in a constant value for diffusion capacity.

(17) Progress: This protocol remains inactive because of other priorities, re-organization of the laboratory and changes in equipment.

Publications: Perry, M.E., Browning, R.J., Kindig, N.B.: The Abbreviated Alveolar Air Equation Revisited. Chest 80:763-764, 1981

**Presentations:**

Kindig, N.B.: DLCO Correction using PaCO Back Pressure Predicted from venous Blood. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO 1981.

Perry, M.E.: Simplified Room Air (A-a)O<sub>2</sub> Calculation. Presented: Carl E. Tempel Pulmonary Symposium, Denver, CO, 1981.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 79/112 (3) Status: Ongoing

(4) Title:  
Use of Sodium Salt of Allopurinol to Control Hyperuricemia in  
Patients with No Therapeutic Alternative. A Pilot Study

(5) Start Date: March 1980

(6) Est Compl Date: Unknown

(7) Principal Investigator:  
Arlene J. Zaloznik, M.D., MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Hem/Oncology

(10) Assoc Investigators:

(11) Key Words:  
Hyperuricemia,  
Allopurinol

Michael Edwards, CPT, MSC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sept 84 b. Review Results: continued

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: Three

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

To determine the effect of a parenteral form of allopurinol to control hyperuricemia when the patient is unable to take the tablet form (commercially available)

(16) Technical Approach:  
Clinical Study

(17) Progress:

No new patients have been entered on this study but it should be kept open since the medication is not commercially available and it may be needed in the patient who requires antitumor therapy but is unable to take oral allopurinol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/115 (3) Status: Ongoing  
(4) Title: Evaluation of Amiodarone for the Therapy of Cardiac Arrhythmias

(5) Start Date: 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Richard C. Davis, Jr., COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Cardiology/Medicine	(10) Assoc Investigators: John T. Svinarich, MAJ, MC
(11) Key Words: amiodarone cardiac arrhythmias	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 5 thru June 85  
d. Total Number of Subjects Enrolled to Date: 15  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To control symptomatic cardiac arrhythmias which have not been responsive to the conventional and accepted forms of treatment or whose control is dependent upon the use of a drug which has been shown to be harmful to or in other ways not tolerated by the individual.

(16) Technical Approach: After patient selection, baseline laboratory results as outlined in the protocol will be obtained. After initiation of therapy, the patient will be followed regularly by the principal investigator with frequent Holter monitors to assess the efficacy of the drug and other laboratory tests and examinations to warn of potential toxicity.

(17) Progress: Five additional patients have been recruited. Three have shown a response -- one patient died of refractory arrhythmias and one developed signs of a peripheral neuropathy and the drug was discontinued.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/117 (3) Status: Terminated

(4) Title: Correlation of Clinical Signs and Symptoms with Assays of Circulating Immune Complexes

(5) Start Date: 1980

(6) Est Compl Date: 1984

(7) Principal Investigator:  
W. Ronald Tipton, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy/Medicine

(10) Assoc Investigators:

(11) Key Words:

immune complexes  
Clq laboratory assays

V. Iyengar, LTC, MC  
Jeneen Nelson, DAC, DCI

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_

b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: The purpose of this study is to determine the relative sensitivity of several laboratory assays for immune complexes in patients with suspected immune complex disorders.

(16) Technical Approach: Patients whose serum is submitted for antinuclear antibody analysis will be clinically assessed and their serum will be evaluated for the presence of circulating immune complex. Three assays for immune complexes (Clq precipitin, anti-Clq precipitin and Clq ELISA) and two newly developed (Anti-Clq ELISA and anti-C3 ELISA) will be evaluated for sensitivity and specificity. Statistical evaluation will determine which of these assays correlates best with clinical disease.

(17) Progress: Approximately 400 serum samples were evaluated by various immune complex assays with the Anti-Clq ELISA demonstrating the greatest sensitivity and specificity. Correlations of immune complex levels with stages of clinical disease could not be firmly established. However, the data generated did result in reportable information and a highly specific and sensitive assay for immune complexes was developed.

Presentations: Iyengar V: Correlation of Clinical Signs and Symptoms with Assays of Circulating Immune Complexes. Presented: Hematology-Oncology Meeting, San Francisco, Sept 84.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80.118D (3) Status: Ongoing

(4) Title:

5-Azacytidine in the Treatment of Acute Lymphocytic Leukemia

(5) Start Date: Nov 80

(6) Est Compl Date: Unknown

(7) Principal Investigator:

(8) Facility: FAMC

Arlene J. Zaloznik, M.D.MAJ,MC

(9) Dept/Svc: Medicine/Hem/Oncology

(10) Assoc Investigators:

(11) Key Words:

5-Azacytidine,  
Acute Leukemia

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sept 84 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 7

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". No adverse drug reactions.

(15) Study Objective:

To determine the efficacy of 5-Azacytidine in patients with acute non-lymphocytic leukemia who have relapsed after conventional chemotherapy.

(16) Technical Approach:

Patients who have proved to be refractory to standard forms of acute leukemia are given 5-Azacytidine in an attempt to induce remission.

(17) Progress

Although no patients have been registered during the last year it is recommended that this protocol continue to be open for patients with refractory leukemia until such time as 5-Azacytidine becomes commercially available.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85	(2) Protocol WU#: 80/120	(3) Status: Ongoing
(4) Title: EVALUATION OF CARBOHYDRATE METABOLISM IN THYROTOXICOSIS: INVESTIGATIONS INTO THE FREQUENCY, TYPE AND MECHANISMS OF CARBOHYDRATE TOLERANCE		
(5) Start Date: April 1981	(6) Est Compl Date: October 1986	
(7) Principal Investigator: Gerald S. Kidd, LTC, MC	(8) Facility: FAMC	
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: T. P. O'Barr, Ph.D., DAC Fred D. Hofeldt, COL, MC (Ret) Robert J. Sjoberg, CPT, MC	
(11) Key Words: carbohydrate intolerance thyrotoxicosis		
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.		
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____		
c. Number of Subjects Enrolled During Reporting Period: <u>1</u>		
d. Total Number of Subjects Enrolled to Date: <u>11</u>		
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A		

(15) Study Objective:

The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance tests. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral or intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach:

Ten non-diabetic patients who are taking no medications, are less than age 45 are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress:

In FY85, one new patient has been studied and 3 patients have been restudied followup phase. Progress has been slow because of unit priorities but work continues.

(1) Date: 30 Sep 85 (2) Protocol WU#:80/121 (3) Status: Ongoing	
(4) Title: AN EVALUATION OF PITUITARY AND THYROID HORMONAL RESPONSE TO A 4-HOUR CONTINUOUS AND A BOLUS INTRAVENOUS INFUSION OF TRH AS A USEFUL TEST OF THYROIDAL FUNCTIONAL RESERVE	
(5) Start Date: March 1981	(6) Est Compl Date: July 1986
(7) Principal Investigator: Michael Bornemann, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, LTC, MC William J. Georgitis, MAJ, MC
(11) Key Words: thyroid functional reserve pituitary thyroid axis TRH infusion	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: 9/84 b. Review Results: Ongoing	
c. Number of Subjects Enrolled During Reporting Period: 4	
d. Total Number of Subjects Enrolled to Date: 38	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None	

(15) Study Objective:

The objective of this study is to determine if the diagnosis of mild or subclinical hypothyroidism can be more clearly established by some integrated parameter reflecting both the pituitary and thyroidal reserve responses to intravenous thyrotropin releasing hormone.

(16) Technical Approach:

Three groups of subjects will be evaluated in this protocol. Group 1 will consist of normal control patients; Group 2 will consist of patients with mild hypothyroidism diagnosed by an elevated TSH level but normal thyroid hormone levels; Group 3 will consist of patients with the Thyroid Clinic with high-normal TSH values and normal thyroid function tests, but who are clinical suspects of having mild hypothyroidism. The patients will undergo two TRH infusion tests in a random manner consisting of conventional bolus administration of 500 ug of TRH solution and the constant infusion of TRH over a 4-hour period with 500 ug of TRH diluted in normal saline and diffused at a rate of 2 ug per minute over the 4 hours using a Harvard infusion pump. The TSH values in the various groups of patients will be determined and statistically analyzed for differences between the groups.

## (17) Progress:

Sufficient data is available on 23 patients and 7 controls. Analysis of data has been hindered by the destruction of the computerized program and data on that program. Although final compilation of the data is not proceeding we request that the protocol stay open to allow more controls to be studied if necessary. No further publications have arisen from this study.

## Presentations:

- (1) Bornemann, M.: Pitfalls in Mild Subclinical Hypothyroidism: Comparison of the TRH Bolus and Infusion. Submitted for Hugh Mahon Lectureship Award, FAMC, May 1983.
- (2) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. (Abst.) Clin. Res. 32:1, 1984.

## Presentations:

- (1) Bornemann, M., Kidd, G.S., and Hofeldt, F.D.: Comparison of Thyrotropin Releasing Hormone Bolus and Infusion Testing in Patients with Suspected Subclinical Hypothyroidism. Presented: Western Section, Western Meeting, Carmel, CA February 1984.

# DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &  
HSPA-I Ltr,  
8 July 1982

(1) Date: FY 1985 (2) Protocol WU Nr.: 81/101 (3) Status: Completed  
(4) Title: Development and Evaluation of Rapid Immunologic Procedures for the  
Diagnosis of Giardiasis.

(5) Start Date: May 1981 (6) Est Compl Date: January 1984  
(7) Principal Investigator: Thomas G. Brewer (8) Facility: FAMC  
FAMC

(9) Dept/Svc: Gastroenterology/DCI Microbiology (10) Assoc Investigators:  
(11) Key Words: Chronic diarrhea Giardiasis, IFA DCI: Inglekirk, Paine, McNally, Herra.

(12) Accumulate MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.  
(14) a. Date, Latest HUC Review: Apr 84 b. Review Results: Approved  
c. Number of subjects enrolled during reporting period: None  
d. Total number of subjects enrolled to date: 36  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND.: N/A

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: To Develop and Evaluate Immunologic Procedures for the  
Diagnosis of Giardiasis.

(16) Technical Approach: We have not deviated from the technical approach previously  
outlined.

(17) Progress: Results of testing for circulating antibodies detected by IFA-technique  
are as reported in the previous protocol summary. No further patient material has been  
entered nor has further work been completed on this study since that time. A draft of  
the report of the results of the prospective study will be forwarded to COL Corby,  
C, Dep of Clinical Investigation within the next 60 days after which time the manuscript  
will be submitted for publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/104 (3) Status: Ongoing  
(4) Title: The Incidence of Host Defense Deficiencies in Patients Presenting with Frequent or Prolonged Infections

(5) Start Date: 1981	(6) Est Compl Date: 1987-88
(7) Principal Investigator: Richard W. Weber, COL, MC	(8) Facility: FAMC

(9) Dept/Svc: Allergy Svc	(10) Assoc Investigators:
(11) Key Words: immunodeficiency infection laboratory tests	Harold S. Nelson, COL, MC William J. Rickman, CPT, MS Joseph Lima, DAC Fellows - Allergy/Immunology Svc

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 3  
d. Total Number of Subjects Enrolled to Date: 15  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the cost effectiveness of performing various laboratory evaluations of immune responsiveness in patients presenting with frequent or prolonged infection.

(16) Technical Approach: Patients who are referred for this protocol will have a standardized clinical evaluation by the Fellows in the Allergy-Immunology Service, and will have a standard batter of tests performed to evaluate their immune status and phagocytic function. On the basis of the clinical history certain laboratory tests will be determined to have been clinically indicated. Subsequently, the yield from those tests which were thought to have been clinically indicated.

(17) Progress: This protocol is continuing. We have enrolled 15 patients. It is anticipated that it will take approximately 5-6 years to accumulate enough patients to complete the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/106 (3) Status: Terminated

(4) Title: Clinical Effectiveness and Development of Subsensitivity with Chronic Administration of Atropine Methonitrate.

(5) Start Date: 1981 (6) Est Compl Date: 1984

(7) Principal Investigator: Harold S. Nelson, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Allergy (10) Assoc Investigators:

(11) Key Words: atropine methonitrate  
bronchodilator subsensitivity Robert E. Bowen, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results: 0  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To measure the bronchodilator response to atropine methonitrate initially and following 2 weeks of regular use.

(16) Technical Approach: The bronchodilator response to nebulized saline and atropine methonitrate will be measured for 2 hrs. on 2 separate days, and the subject will be given either saline or atropine methonitrate to employ at home by nebulization four times daily. At the end of 2 wks. the patient will return and receive the same medication that he had employed for the previous 2wks., and again pulmonary function response will be followed for 2 hrs. There upon the patient will cross over, receiving the alternate saline or atropine methonitrate at home four times a day, and return at the end of 2 wks to again receive the medication utilized during those 2 wks and have the pulmonary function measured for 2 hrs.

(17) Progress: No patients were studied employing atropine sulfate.

# DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &  
HSPA-I Ltr,  
8 July 1982

(1) Date: FY 85 (2) Protocol WU Nr.: 81-115 (3) Status: Terminated  
(4) Title: Comparison of Modalities for Treatment of SLE Nephritis.

(5) Start Date: 1982 (6) Est Compl Date: 1985  
(7) Principal Investigator (8) Facility: FAMC  
Sterling G. West, M.D. and Peter A. Andersen, M.D.  
Major, MC Major, MC  
Chief, Rheumatology Service AsstC, Rheumatology Service

(9) Dept/Svc: Rheumatology (10) Assoc Investigators:  
(11) Key Words: SLE Nephritis, Mark Nelson, M.D., Major MC, C, Rheuma-  
steroids, chlorambucil tology, WBAMC

(12) Accumulate MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.  
(14) a. Date, Latest HUC Review: Sep 1984b. Review Results:  
c. Number of subjects enrolled during reporting period: One  
d. Total number of subjects enrolled to date: Eight  
e. Note any adverse drug reactions reported to the FDA or sponsor for  
studies conducted under an FDA-awarded IND.: None

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: To evaluate the efficacy and side effects of single daily dose of corticosteroid versus split dose steroid therapy and b) To provide an alternative form of therapy in patients with SLE nephritis that have not responded to conventional steroids and to evaluate the patient's clinical  
(16) Technical Approach: Patients with lupus nephritis are randomly assigned after form consent to one of two modes of therapy-either split dose or single dose steroids. A variety of serologic parameters are monitored indicating their response to these medications. Patients who do not respond to this therapy  
(17) Progress: Over the past three years of this study, the two other medical centers involved have lost both their rheumatologists. The rheumatologists who have come in to take their places have indicated that they are not interested in continuing the protocol. Since this would mean that Fitzsimons would be the only medical center entering patients, I can predict that we will not be able to get the required number within a reasonable period of time. Consequently, I am requesting termination of this protocol. We plan to enter future patients with lupus nephritis into a combined protocol with Stanford and the National Institute of Health which will be submitted to the Clinical Investigation Service shortly.

Detailed Summary Sheet Continued

(15) and serologic response to therapy.

(16) are randomalized to either receiving high dose pulse steroids or chlorambucil again on a random method. Again, serologic parameters are followed to indicate response to this therapy.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/117 (3) Status: Completed  
(4) Title:

THE ROLE OF CALCITONIN IN OSTEOPOROSIS

(5) Start Date: November 1982	(6) Est Compl Date: Completed
(7) Principal Investigator: Michael T. McDermott, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Gerald S. Kidd, LTC, MC Peter Blue, LTC, MC Nasser Ghaed, COL, MC Fred D. Hofeldt, MD
(11) Key Words: osteoporosis calcitonin deficiency bone density	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: Nov 82 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 60  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

None.

(15) Study Objective:

The objectives of this study are to further investigate the role of calcitonin, or its deficiency, in the development of osteoporosis and to determine if thyroidectomized patients, who are calcitonin deficient, are at increased risk of developing osteoporosis.

(16) Technical Approach:

Four groups of individuals are studied with bone densitometry using the Norland apparatus. A control group of normals and a thyroid suppressed group of patients compared with a group of thyroidectomized patients who are therefore calcitonin deficient.

(17) Progress:

Sixty patients have completed the study. Final data is currently being analyzed. Initial data was previously published and the second manuscript is now being written.

SERVICE EndocrineDEPARTMENT Medicine

- (1) McDermott M., Kidd, G., Blue, P., et al: Bone mineral content in totally thyroidectomized patients; possible effect of calcitonin deficiency. (Abst.) 64th Meeting of the Endocrine Society, San Francisco, CA, June 1982.
- (2) McDermott, M.D., Kidd, G.S., Blue, P., Ghaed, V., and Hofeldt, F.D.: Reduced Bone Mineral Content in Totally Thyroidectomized Patients: Possible Effect of Calcitonin Deficiency. J. Clin. Endocrinol. Metab. 56:936-939, 1983.

## Presentations:

- (1) McDermott, M.T.: Bone Mineral Content in Totally Thyroidectomized Patients. -Presented: Uniformed Services Society of Endocrinology, San Francisco, CA, June 1982.

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/118 (3) Status: Ongoing

(4) Title:

HYPOTHALAMIC PITUITARY GONADAL FUNCTION IN HYPOTHYROIDISM

(5) Start Date: Sep 81

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:

(11) Key Words:

hypothyroidism  
HPG axis  
gonadal function

Gerald S. Kidd, LTC, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Nov 82 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach:

A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress:

One patient has been studied and her frozen serum has not yet been assayed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 81-121-N (3) Status: Completed

(4) Title:

IgA Nephropathy: A Prospective Evaluation

(5) Start Date: Dec. 81

(6) Est Compl Date: Terminated

(7) Principal Investigator:

(8) Facility: FAMC

JAMES A. HASBARGEN, MD

MAJOR, M.C.

Chief, Nephrology Service

(9) Dept/Svc: ~~Medicine/Nephrology~~

(10) Assoc Investigators:

(11) Key Words: IgA nephropathy,

Berger's Disease, prospective evaluation

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine pathologic and clinical pathologic criteria for the diagnosis of IgA nephropathy, prognosis of patients with such a diagnosis, suitability for continued military service. The extent of the evaluation and degree of follow up required for such patients, and the sensitivity and specificity of various non-invasive diagnostic techniques which potentially could obviate the necessary for renal biopsy.

(16) Technical Approach: Patients who meet patient selection criteria established in protocol enrolled and subjected to the following: skin biopsy, serum IgA level, IgA coated peripheral lymphocyte analysis, and HLA typing. In addition, a kidney biopsy is closely scrutinized and the patient examined reference symptoms accompanying their disease and other associated symptomatology. Follow up is conducted indefinitely at six month intervals and if patient develops a marked decrease in renal function, kidney biopsy is repeated. Repeat skin biopsy is accomplished only for episodes of gross hematuria.

(17) Progress: Due to personnel time constraint, enrollment in the protocol has terminated. One paper has been published in the past year on this. See Publication portion.

SERVICE Nephrology

DEPARTMENT Medicine

PUBLICATIONS:

1. Utility of Skin Biopsy to Include Use of Histamine in Diagnosis of IgA Nephropathy. J. Hasbargen and J. Copley. Proceedings of IX International Congress of Nephrology 1984.

2. Utility of Skin Biopsy in the Diagnosis of IgA Nephropathy. J. Hasbargen, and J. Copley. American Journal of Kidney Diseases, Vol VI, No 2, August, 1985.

PRESENTATIONS:

1. Presented: 4th International Congress of Nephrology, Los Angeles, California, June 1984.

2. Tapp, D., Copley, J. Hasbargen, J. Moore, J. Gouge, S., Antonovych, V. and Guggenheim, S.: Presented: IgA Nephropathy and Pathologic Correlation. Current Concepts in Internal Medicine, San Francisco, CA October 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/123 (3) Status: Completed

(4) Title:

Primary Renal Hematuria: A Prospective Evaluation

(5) Start Date: Feb. 82

(6) Est Compl Date: Terminated

(7) Principal Investigator:

(8) Facility: FAMC

James A. Hasbargen, MD  
MAJ, M.C.  
Chief, Nephrology Service

(9) Dept/Svc: ~~Medicine/Nephrology~~

(10) Assoc Investigators:

(11) Key Words:

Primary renal hematuria,  
prospective evaluation

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 9

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the etiology and significance of hematuria microscopic and macroscopic, as well as prognosis in patients who have neither personal or family history of renal disease, nor evidence of systemic disease or extra renal causes of hematuria.

(16) Technical Approach: Patients who meet established criteria contained within the protocol are evaluated with skin biopsy, serum IgA levels and IgA coated peripheral lymphocytes. Most patients then undergo renal biopsy and/or renal arteriography (dependent upon age). HLA typing is accomplished on all patients and patients are followed every six months for an indefinite period of time regardless of renal biopsy findings to determine the course of their disease.

(17) Progress: The study enrollment has terminated secondary to personnel time constraint and the fact that a total of 65 patients were enrolled. A manuscript has been prepared and is currently in the submission process.

Publications: Copley, J.B., and Hasbargen, J.A. "Primary Hematuria" A Prospective Evaluation (Abstract). Kidney International, 25:161, 1984.

Presentations: Copley, J.B., and Hasbargen, J.A. "Primary hematuria": A Prospective Evaluation. Presented: Am Soc Neph Conf, December 1984.

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/125 (3) Status: Terminated  
 (4) Title: Flexible Fibroptic Esophageal Vein Sclerosis (Sclerotherapy:  
 A Multicenter Study)

(5) Start Date: September 1981	(6) Est Compl Date: June 1984
(7) Principal Investigator: Thomas G. Brewer	(8) Facility: FAMC
(9) Dept/Svc: Gastroenterology	(10) Assoc Investigators:
(11) Key Words: esophageal varices fibroptic vein sclerosis	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: June 84 b. Review Results: Approved  
 c. Number of Subjects Enrolled During Reporting Period: none  
 d. Total Number of Subjects Enrolled to Date: 5  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine the therapeutic efficacy and safety of flexible fibroptic vein sclerosis and preventing recurrent bleeding in patients with recurrent hemorrhage esophageal varices.

(16) Technical Approach: We have noted deviated from the technical approach to sclerosing esophageal varices as outlined in the protocol. Endoscopic sclerotherapy has been accomplished in all five patients entered in the study with a maximum number of sclerotherapies accomplished being six in one study patient. Olympus single channeled or double channeled panendoscopes have been used with Olympus and Medi Teck injectors which contain a retractable 23-gauge needles with three percent Sotradecol (Sodium Tetradecyl Sulfate - TSS).

(17) Progress: Five of the 37 patients enrolled in this study were enrolled at Fitzsimons - all in the sclerotherapy group. Since no further patients were entered from any of the Denver groups after mid 1983, the protocol activity has been terminated and patients have continued to be followed in this clinic with periodic clinical visits and sclerotherapy as clinically indicated. Two of the five patients in the FAMC group are deceased due to non-study related factors including intercerebral hemorrhage (one patient) and death from terminal hepatic

PROGRESS - continued

encephalopathy (one patient). No recurrent varicele hemorrhage has been noted in any FAMC patient in the protocol and no late or long term adverse effects from sclerotherapy (esophageal stricture, ulceration, perforation or dysmotility) have been noted.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:82/100-N (3) Status: Ongoing  
(4) Title: Combined Prednisone and Cyclophosphamide Therapy Coupled with Plasma  
In The Treatment of Anti-glomerular Basement Membrane (Anti-GBM) Antibody Induced  
Disease.

(5) Start Date: Mar 82 (6) Est Compl Date: 86  
(7) Principal Investigator: (8) Facility: FAMC

JAMES A. HASBARGEN, MD  
MAJ, M.C.  
Chief, Nephrology Service

(9) Dept/Svc: Medicine/Nephrology (10) Assoc Investigators:  
(11) Key Words:  
Prednisone, Cyclophosphamide  
Plasmapheresis, anti-GBM  
antibody induced disease

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine if Prednisone and Cyclophosphamide alone or in combination with plasmapheresis is efficacious in lowering circulating anti-GBM bi-levels and thereby affecting the clinical course of anti-GBM induced nephritis. In addition, it is desirable to learn if treatment with Prednisone and Cytotoxin with or without plasmapheresis has a role in the prevention of, or is therapeutic for pulmonary manifestations of anti-GBM induced disease.

(16) Technical Approach: Patients with anti-GBM antibody disease are randomized in one to two treatment groups consisting of Prednisone and Cyclophosphamide alone or combination with plasmapheresis. Patients are monitored with history, physical, he logic and chemistry monitoring to include renal function parameters as well as anti antibody titers. Criteria for withdrawal from the study as well as analysis of the study are indicated within the protocol.

(17) Progress: No changes from last year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/101 N (3) Status: Ongoing  
(4) Title:

Steroid and Immunosuppressive Drug Therapy In Idiopathic Crescentic Glomerulonephritis

(5) Start Date: Apr 82 (6) Est Compl Date: Apr 86  
(7) Principal Investigator: (8) Facility: FAMC

JAMES A. HASBARGEN  
MAJ, M.C.  
Chief, Nephrology Service

(9) Dept/Svc: Medicine/Nephrology (10) Assoc Investigators:  
(11) Key Words: steroid  
immunosuppressive drug, idiopathic  
crescentic, glomerulonephritis,  
rapidly progressive glomerulonephritis  
JAMES E. BALOW, MD and HOWARD A. AUSTIN,  
National Institutes of Health  
Bethesda, Maryland

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 1  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To compare the efficacy of intravenous methylprednisolone vs. intravenous cyclophosphamide in the treatment of idiopathic crescentic glomerulonephritis. Comparison will be made of the number of favorable outcomes of renal function and renal pathology as well as drug related toxicities manifested by each treatment group at the time of the 6 study month.

(16) Technical Approach: Patients with idiopathic crescentic glomerulonephritis are randomized into one of two study groups to receive either monthly intravenous pulse methylprednisolone for six months or monthly intravenous pulse cyclophosphamide for 6 months. All patients are treated with oral prednisolone in addition. Effects of therapy are monitored with frequent histories and physical examinations as well as hematologic, urinalysis and renal function monitoring. At the end of 6 months a second renal biopsy is accomplished to determine the effect of the above mentioned therapy. Criteria for withdrawal from the study, retreatment of patients who exacerbate their course of glomerulonephritis, and analysis of the study are as indicated in the study protocol.

(17) Progress: No change from last year.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/104 (3) Status: Ongoing

(4) Title: THE EFFECT OF TAMOXIFEN ON GYNECOMASTIA

(5) Start Date: 30 Sep 82 (6) Est Compl Date: March 1987

(7) Principal Investigator: Michael T. McDermott, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine (10) Assoc Investigators: Fred D. Hofeldt, MD  
(11) Key Words: tamoxifen gynecomastia therapy Gerald S. Kidd, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Feb 83 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 6  
d. Total Number of Subjects Enrolled to Date: 6  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:  
The objective of this protocol is to evaluate, in a double-blind placebo controlled prospective trial, the effect of Tamoxifen on males with gynecomastia and to characterize any co-existent hormonal changes.

(16) Technical Approach:  
A randomized, double-blind placebo controlled study of the effect of Tamoxifen therapy on idiopathic gynecomastia will be performed. Breast size will be assessed by photographs, palpation and measurement of tissue.

(17) Progress:  
Six patients have entered the study; one dropped out for no apparent reason. Four have completed the study. One had improvement in size and tenderness. One had reduced size only, one had reduced tenderness only, and one did not improve. One other is currently being studied.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:82/106 (3) Status: Terminated  
(4) Title: Clinical Usage of High Frequency Jet Ventilation

(5) Start Date: 1981	(6) Est Compl Date: 1985
(7) Principal Investigator: Michael Perry, COL, MC	(8) Facility: FAMC

(9) Dept/Svc: Med/Pulmonary	(10) Assoc Investigators:
(11) Key Words: high frequency jet ventilation	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 2  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". n/a

(15) Study Objective: All patients with bronchopleural fistulae or who are difficult to ventilate with standard technique are candidates for this mode of ventilation. Assessment will be made concerning the efficacy of high frequency jet ventilation for the various clinical problems encountered.

(16) Technical Approach: A standard VS 600 jet ventilator will be used with an injection catheter placed into the endotracheal tube. Adjustment of driving pressures (up to #50/sq in) will be made along with I:E ratio for maximum ventilation and oxygenation.

(17) Progress: Terminated since approval of human use has been unavailable because of the too stringent protocol criteria.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/109 (3) Status: *Terminated*

(4) Title: *Correlation of Birth Weight with Maternal Hemoglobin S.  
Concentration: A Retrospective Study*

(5) Start Date: 1982

(6) Est Compl Date: *Terminate*

(7) Principal Investigator:

(8) Facility: FAMC

*John R. Hess, LTC, MC*

(9) Dept/Svc: *MED/Hem/Onc*

(10) Assoc Investigators:

(11) Key Words:

*hemoglobin S  
Sickle cell trait*

*J. Benjamin Hall, MAJ, MC  
Lynn G. Stansbury, M.D., DAC  
Jay M. Hill, COL, MC*

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_

d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: *a) To reaccess the association of maternal sickle cell trait and low infant birth weight. b) To correlate infant birth weight with maternal hemoglobin S concentration.*

(16) Technical Approach: *The relation of infants birth weight to their mothers' levels of Hb S and duration of gestation will be accessed with the techniques of linear and multiple linear regression or analysis of variance and covariance. Difference will be judged significant at the .05 level.*

(17) Progress: *The numbers are too small and the study would need to continue for 10 to 15 years for statistical significance. Terminate.*

Publication and Presentations: *NONE*

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/111 (3) Status: completed	
(4) Title: Investigation of the efficacy and side effects of oral and inhaled beta adrenergic bronchodilators in patients on optimal theophylline therapy.	
(5) Start Date: 1983	(6) Est Compl Date: Sep 85
(7) Principal Investigator: HS Nelson, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MED/All.	(10) Assoc Investigators:
(11) Key Words: Adrenergic bronchodilator subsensitivity	Mark L. Vandewalker, MAJ, MC
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	
(13) Est Accum OMA Cost:*	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period: 0	
d. Total Number of Subjects Enrolled to Date: 25	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	

none

(15) Study Objective: To determine whether the addition of oral or inhaled beta adrenergic medication to treatment with optimal doses of theophylline significantly improves the treatment of patients with bronchial asthma.

16) Technical Approach: Patients will be placed on oral theophylline and either oral or inhaled terbutaline. They will then undergo a double-blind crossover of terbutaline and placebo. During this time pulmonary function and asthma symptoms and requirement for asthma medication will be monitored.

17) Progress: Twenty patients completed the usable data for the oral phase of the study and 13 of these individuals also completed the inhaled phase.

Publications: None

Presentations for FY 85 Annual Progress Report

Proto No. 82/111

SERVICE Allergy

DEPARTMENT Med.

Kray, KT, Vandewalker, ML, Weber, RW, Nelson, HS: Double-blind study of long-term oral terbutaline: Efficacy and side effects. Presented 37th Annual Fitzsimons Symposium 23-25 Jan 85.

Kray, KT: Double-blind study of long-term oral terbutaline: Efficacy and side effects . Presented 41st annual meeting Am. Acad. of Allergy & Imm. New York NY March 16-20, 1985

Vandewalker, ML: Double-blind crossover study of inhaled terbutaline in asthmatics on optimal theophylline therapy. Presented 37th Annual FAMC Symposium 23-25 Jan85

Vandewalker, ML, Kray, KT, Weber, RW, Nelson, HS: Double-blind crossover study of long-term inhaled terbutaline. Presented 41st annual Congress of Am. College of All. , Balhaour, FL, 2-6 Feb 85.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/113 (3) Status: terminated

(4) Title: The effect of inhaled corticosteroids on the development of beta adrenergic subsensitivity.

(5) Start Date: *not started*

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

HS Nelson, COL, MC

Allergy-Immunology Service

(9) Dept/Svc: MED/Allergy

(10) Assoc Investigators:

(11) Key Words:

corticosteroids

beta adrenergic subsensitivity

RW Weber, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

none

(15) Study Objective:

To determine whether the administration of inhaled corticosteroids in conjunction with inhaled beta adrenergic bronchodilators prevents the development of subsensitivity to the bronchodilator action of the beta agonists.

16) Technical Approach: Patients will be tested for their response to inhaled terbutaline before and after a 3-week course of inhaled terbutaline or placebo administered in a double-blind, random crossover design.

17) Progress: This study had been postponed until completion of the ketotifen beta adrenergic subsensitivity study.

Publications and Presentations None

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/114 (3) Status: Ongoing  
 (4) Title: Growth of Basal Cell Carcinoma Cells in Defined Medium and Study of their growth and Immunological Characteristics

(5) Start Date: Nov 82	(6) Est Compl Date: Oct 86
(7) Principal Investigator: Charles F. Ferris, Ph.D. CPT, MS	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators: Ronald W. Grimwood, M.D. J. Clark Huff, M.D. Richard A.F. Clark, M.D.
(11) Key Words: basal cell carcinoma defined culture media for keratinocytes	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: Growth and study of basal cell carcinoma cells in culture.

(16) Technical Approach: The approach to culturing of basal cells has, and will be the use of the media formulated by Dr. Ham's lab at the University of Colorado in Boulder termed MCDB 153. We have been successful to date in culturing normal cell carcinomas. This has included an attempt utilizing fibronectin coated plate. We next will be attempting growth utilizing basal cell tumors that we have successfully grown in nude mice. There is experimental evidence with other tumors grown in nude mice to suggest that there is a greater success rate of in vitro culture once the tumors have been grown in the animal model.

(17) Progress: Problems have been encountered with the MCDB 153 media. This has necessitated an effort to remedy the media problem before growth of basal cells can take place.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/115 (3) Status: Terminated	
(4) Title: Serial Two-Dimensional Echocardiographic Evaluation of Acute Anterior Myocardial Infarctions for Detection of Left Ventricular Thrombi	
(5) Start Date: November 1982	(6) Est Compl Date:
(7) Principal Investigator: Guy N. Piegari, Jr, MD, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Cardiology	(10) Assoc Investigators: Richard C. Davis, Jr., MD, PhD, LTC, MC Harry M. Thomas, Jr., MD, COL, MC
(11) Key Words: 2-D echocardiography left ventricular thrombi	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: NA b. Review Results: NA	
c. Number of Subjects Enrolled During Reporting Period: NA	
d. Total Number of Subjects Enrolled to Date: NA	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA	
(15) Study Objective: Assess incidence of mural thrombi in patients with acute anterior MI.	
(16) Technical Approach: Patients admitted to CCU with acute anterior MI receive serial 2-D echocardiogram over 10-day period.	
(17) Progress: Since transfer of original principal investigator, this study has been on hold status. No progress have been made in FY85. An appropriate principal investigator has not been found.	
Publications and Presentations: None.	

# DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &  
HSPA-I Ltr,  
8 July 1982

(1) Date: FY 30 Sep 85(2) Protocol WU Nr.: 82-116 (3) Status: Terminated

(4) Title:

ASSESSMENT OF REGIONAL WALL MOTION ABNORMALITIES BY RADIONUCLIDE ANGIOGRAPHY,  
EFFECT OF SUBLINGUAL NITROGLYCERIN

(5) Start Date: 1982

(6) Est Compl Date: 1985

(7) Principal Investigator

(8) Facility: FAMC

STEVEN J RAIBLE MD MAJ MC

(9) Dept/Svc: Medicine/Cardiology

(10) Assoc Investigators:

(11) Key Words:

Richard C. Davis Jr MD, PhD, COL MC

RVG

John Jackson, MD, MAJ, MC

nitroglycerin

Peter W. Blue MD LTC MC

introlycerin

angiography

(12) Accumulate MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA

b. Review Results: NA

c. Number of subjects enrolled during reporting period: 0

d. Total number of subjects enrolled to date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.: 0

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: This study is designed to analyze the sensitivity and specificity of radionuclide angiography in assessing segmental wall motion abnormalities after nitroglycerin administration and after coronary artery bypass grafting.

(16) Technical Approach: Forty patients with stable angina and atherosclerotic heart disease involving one or more vessels with a wall motion abnormality documented by cardiac catheterization within six months prior to gated radionuclide ventriculography (RVG) will be studied. Patients will be between the ages of 30 and 65. No study candidate will have had a prior transmural myocardial infarction or have aortic or mitral valvular heart disease. Those patients undergoing coronary artery bypass grafting will have repeat RVG approximately 10 days after surgery. All patients will be tested in a basal fasting state and will have all nitroglycerin preparations withheld for 24 hours prior to the study.

(17) Progress: No accountable progress has been made on this study due to technical problems, finding suitable patients and arranging suitable time with physicians and technicians.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/101 (3) Status: Ongoing	
(4) Title: Genetics of Exfoliatin B Production from Clinical Isolates of Staphylococcus aureus	
(5) Start Date: February 1983	(6) Est Compl Date: December 1986
(7) Principal Investigator: Steven M Opal, MD MAJ MC	(8) Facility: FAMC
(9) Dept/Svc: DOM, Inf Dis DCI	(10) Assoc Investigators: Pari L. Morse, GS-9
(11) Key Words: Exfoliatin B Staphylococcal plasmids	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: NA b. Review Results: NA	
c. Number of Subjects Enrolled During Reporting Period: NA	
d. Total Number of Subjects Enrolled to Date: NA	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

(15) Study Objective:

The objective of this study is to isolate plasmid DNA responsible for the production of exfoliatin B production in Staphylococcus aureus strains. The restriction endonuclease digestion pattern of this isolate will be compared with that of other exfoliatin B producers as well as reference strains from the CDC.

(16) Technical Approach:

Staphylococcal plasmid DNA was isolated by cleared lysis technique and by cesium chloride ultracentrifugation density gradients. The isolated plasmid DNA was then run on agarose gel electrophoresis for molecular weight sizing. The endonuclease digestion pattern will then be obtained by digesting this plasmid with restriction endonuclease enzymes.

(17) Progress:

The initial plasmid isolation and characterization of the plasmid molecular weight on agarose gel has been accomplished. To date, the digestion with restriction endonuclease enzymes has not been successful. It is assumed that the first batch of enzymes were not effective, therefore when budgetary conditions allow, new enzymes will be ordered and the procedure completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/102 (3) Status: Complete  
 (4) Title: A Survey of Extrachromosomal Elements of Legionella pneumophila Serotype 1, from Environmental and Clinical Isolates.

(5) Start Date: February 1983	(6) Est Compl Date: December 1984
(7) Principal Investigator: Steven M. Opal, MD, MAJ, MC Carol Ciesielski, MD, Inf. Diseases, CU Med Center	(8) Facility: FAMC

(9) Dept/Svc: DOM, Inf. Dis.	(10) Assoc Investigators: Pari L. Morse, GS-9 Paul G. Englekirk, LTC, MSC
(11) Key Words: <u>Legionella pneumophila</u> Serotype I, virulence plasmids	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA  
 c. Number of Subjects Enrolled During Reporting Period: NA  
 d. Total Number of Subjects Enrolled to Date: NA  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:  
 The objective of this protocol is to isolate the plasmid DNA of several environmental and clinical isolates of L. pneumophila, and to compare their plasmid profiles.

(16) Technical Approach:  
L. pneumophila plasmid DNA will be prepared by rapid alkaline precipitation method and analyzed by agarose gel electrophoresis.

(17) Progress:  
 59 environmental and clinical isolates of L. pneumophila were subjected to plasmid DNA analysis. Plasmids were found in many of the isolates, both environmental and clinical. The determination of specific molecular weights was to be completed by the CU Med Center staff, but has not been done. Recently, Dr. Ciesielski has transferred to CDC, Atlanta. Due to these problems, the study has been terminated and a manuscript is in progress describing the plasmid isolation results.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/103 (3) Status: Terminated

(4) Title:  
Role of Vitamin K in Bone Metabolism

(5) Start Date: 1983 (6) Est Compl Date: 1985

(7) Principal Investigator:  
V.G. Iyengar (8) Facility: FAMC

(9) Dept/Svc: Med/Hema/Onco (10) Assoc Investigators:

(11) Key Words:  
bone density measurements

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 9

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this protocol is to find out in a cross-sectional study with control if Coumadin in long-term therapeutic doses can induce significant osteopenia or osteoporosis.

(16) Technical Approach: Patients on Coumadin for more than 1 year and age matched male controls undergo one time interview with the investigator. One time laboratory tests to include: CBC, SMA-18, PT, PTT, 24 urine, calcium and phosphorus, serum FSH, LH, testosterone, PTH, serum ionized calcium and bone density measurements are obtained after obtaining informed consent.

(17) Progress: No patients this FY, terminate study.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/106 (3) Status: Ongoing

(4) Title: Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A Double-Blind Crossover Study

(5) Start Date: 1983

(6) Est Compl Date:

(7) Principal Investigator:

Peter A. Andersen, M.D.  
Sterling G. West, M.D.

(8) Facility: FAMC

FAMC  
Walter Reed Army Medical  
Brooke Army Medical Center

(9) Dept/Spec: Medicine/Rheumatology

(11) Key Words:

methotrexate  
rheumatoid arthritis

(10) Assoc Investigators:

Robert G. Claypool, MD  
Richard C. Welton, M.D.  
Charles S. Via, M.D.

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 7/85 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 15

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: Evaluate effectiveness of weekly pulse MTX to control activity of RA in patients who have failed therapy with gold shots and D-Penicillamine; evaluate the potential of weekly pulse MTX to halt or decrease the progress of destructive changes of articular cartilage and bone and to evaluate the potential for toxicity of weekly pulse MTX.

(16) Technical Approach: Part I - 27 week double blind crossover study of MTX vs placebo comparing joint counts, functional tests, laboratory parameters and subjective scores. Part II - Blinded comparison of pretreatment and 6 month sequential roentgenographs of involved joints. Part III - Evaluation of biochemical liver function studies and comparison with sequential changes on liver biopsy.

(17) Progress: Completion of the double blinded portion of the protocol. We are continuing to accumulate data on patients being treated with rheumatoid arthritis in regard to Part II and Part III of the study being long-term evaluation of radiographic change and potential hepatic toxicity. All patients enrolled completed the double blinded portion of the protocol with exception of one patient who moved from the study area. All patients exhibited some improvement during the active therapy portion of the protocol. There were no adverse reactions at FAMC requiring discontinuation of the protocol. We have established significant evidence to support efficacy of Methotrexate in rheumatoid arthritis for Part III of the protocol.

(17) Progress - continued

Current evaluation of risks versus benefits show marked clinical benefit with no significant adverse affects to date.

Publications:

Andersen, P.A., et al: Weekly Pulse Methotrexate in Rheumatoid Arthritis.  
Ann Int Med 103:489-496, October 1985.

Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/107 (3) Status: ongoing  
 (4) Title:

## USE OF ISOTRETINOIN IN PREVENTION OF BASAL CELL CARCINOMA

(5) Start Date: 1 Oct 84 (6) Est Compl Date: 1990  
 (7) Principal Investigator: J. Ramsey Mellette, M.D. COL, MC  
 (8) Facility: FAMC

(9) Dept/Svc: Medicine/Dermatology (10) Assoc Investigators:  
 (11) Key Words: William Paull, M.D., CPT, MC  
 ISOTRETINOIN  
 RETINOLIDS  
 BASAL CELL CARCINOMA

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: n/a b. Review Results: n/a  
 c. Number of Subjects Enrolled During Reporting Period: 45  
 d. Total Number of Subjects Enrolled to Date: 45  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". Dry skin, chapped lips, myalgias, mildly elevated triglycerides.

## (15) Study Objective:

- a. To evaluate the effectiveness of low dosage levels of Isotretinoin in reducing the incidence of basal cell carcinomas in high risk population.
- b. To examine possible side effects with long term administration of isotretinoin

## (16) Technical Approach:

The study is a double-blind study with participants randomly assigned to the medication. Patients will take the med for three years and will be followed for an additional two years for a total of five years. Compliance side-effects and basal cells are monitored.

## (17) Progress:

Since the onset of the study (October 1984) until 23 September 1985 45 patients have been randomized. Of the forty five patients one has dropped out, three patients have relocated or are currently in the process of relocation. Of the patients who have relocated one continues to return for follow ups, one will be taken off the study medication, and one patient may be transferred to another study site if he is agreeable. Recruitment is ongoing and will continue until August 1986. Potential drug reactions that have been documented include: dry skin, chapped lips, myalgias, mildly elevated triglycerides and blurred vision. Appropriate dose modification or discontinuing of the study medication has taken place as outlined according to the protocol.

Publications: none  
 Presentations: none

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/109 (3) Status: Terminated  
(4) Title:

EARLY REGIONAL WALL MOTION ABNORMALITIES IN NON-TRANSMURAL MYOCARDIAL  
INFARCTION

(5) Start Date: Mar 1983	(6) Est Compl Date: Terminated
(7) Principal Investigator: Matthew J McMahon DO MAJ MC	(8) Facility: FAMC

(9) Dept/Svc: Dept Medicine/Cardio	(10) Assoc Investigators:
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(11) Key Words: Echocardiography Myocardial infarction	Richard C. Davis Jr MD PhD COL MC Guy N. Piegari, JR MD MAJ MC
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(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA  
c. Number of Subjects Enrolled During Reporting Period: 17  
d. Total Number of Subjects Enrolled to Date: 17  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NA

(15) Study Objective:

To assess the utility of two-dimensional echocardiography in facilitating the early diagnosis of non-transmural myocardial infarction.

(16) Technical approach:

Patients entering the FAMC CCU are given: 2-D echocardiography examination within 12 hours of admission. These studies are then evaluated for cardiac wall motion abnormalities. The study is applied only to those patients admitted for chest pain without obvious transmural MI.

(17) Progress:

The principal investigator, Major McMahon, was transferred in July 1985, and the study has been terminated.

Publications and presentations: None.

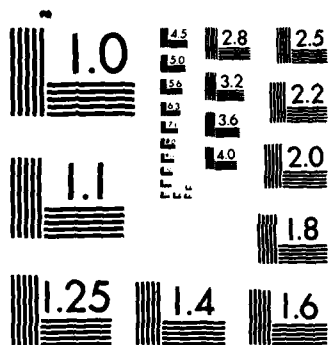
CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT  
(U) FITZSIMONS ARMY MEDICAL CENTER AURORA CO D G CORBY  
30 SEP 85

(U) FITZS  
30 SEP 85

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MICROCOPY RESOLUTION TEST CHART  
NATIONAL BUREAU OF STANDARDS-1963-A

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/113 (3) Status: Ongoing  
(4) Title:

Growth of Human Keratinocytes

(5) Start Date: July 1983	(6) Est Compl Date: July 1986
(7) Principal Investigator: Charles F. Ferris, Ph.D. CPT, MS	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators: Ronald E. Grimwood, M.D. J. Clark Huff, M.D. Phillip T. O'Barr, Ph.D., DAC
(11) Key Words: cell culture keratinocytes	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: Growth and study of human kertainocytes in culture.

(16) Technical Approach: The technical approach as stated last year has been to grow human keratinocytes obtained from newborn foreskins in MCDB 153 serum free medium. This has been accomplished and cells have been successfully frozen down in liquid nitorgen and subsequently cultured. We have not accomplished the final phase which will be to attempt to identify specific antigens (i.e., bullous pemphigoid) expressed by these cells. This will be accomplished with SDS page gel electrophoresis and nitrocellulose transfer.

(17) Progress: Problems have been encountered with the MCDB 153 serum free media both in this laboratory and in Dr. Huff's. A cooperative effort is being undertaken to alleviate the problem so that the cells may be grown for use in various research projects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/115D (3) Status: on-going  
 (4) Title: The effect of oral ketotifen on the development of subsensitivity to beta agonists.

(5) Start Date: 1984	(6) Est Compl Date: 1986
(7) Principal Investigator: H.S. Nelson M.D., COL MC	(8) Facility: FAMC Allergy-Immunology Clinica
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: ketotifen subsensitivity beta agonists	R.W. Weber, M.D., COL MC W. Dolen, M.D., MAJ MC D. Goodman, M.D., CDR MC M. Muggelberg, M.D., MAJ MC

(12) Accumulative MEDCASE: \* (13) Est Accum OMA Cost: \*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 6  
 d. Total Number of Subjects Enrolled to Date: 6  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

none

(15) Study Objective: To determine whether the drug ketotifen can prevent the development of subsensitivity to inhaled beta agonists in humans.

(16) Technical Approach: The bronchodilator response to inhaled terbutaline will be measured before and after chronic terbutaline administration during two periods of time, one when the patients are receiving in addition oral ketotifen, the second when they are receiving a placebo.

(17) Progress: The study has commenced with approximately  $\frac{1}{4}$  of the needed patients enrolled to date.

Publications and Presentations: None

- |   |  |
|---|--|
| (1) Date: 30 Sep 85 (2) Protocol WU#: 83/117 (3) Status: Ongoing  |  |
| (4) Title: THE ROLE OF ALTERED ARACHIDONIC ACID METABOLISM IN THE ATHEROGENESIS AND BLEEDING TENDENCY OF HYPOTHYROIDISM, AND THE RESPONSE OF THIS SYSTEM TO THYROID HORMONE REPLACEMENT |  |
| (5) Start Date: 1 Aug 83  | (6) Est Compl Date: Oct 86   |
| (7) Principal Investigator:<br>Gerald S. Kidd, LTC, MC<br>Robert J. Sjoberg, CPT, MC<br>T. P. O'Barr, Ph.D., DAC<br>Ellen Swanson, MS, DAC  | (8) Facility: FAMC   |
| (9) Dept/Svc: Medicine/Endocrine  | (10) <del>Assoc</del> Investigators: (Cont)                          |
| (11) Key Words:<br>arachidonic acid metabolism<br>hypothyroidism<br>PGI <sub>3</sub> , TxA <sub>2</sub> , B <sub>2</sub>  | Principal<br>Donald Corby, COL, MC<br>Fred D. Hofeldt, COL, MC (Ret) |
| (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*   |  |
| *Refer to Unit Summary Sheet of this report.  |  |
| (14) a. Date, Latest HUC Review: _____ b. Review Results: _____   |  |
| c. Number of Subjects Enrolled During Reporting Period: N/A   |  |
| d. Total Number of Subjects Enrolled to Date: Animal Study  |  |
| e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A |  |

## (15) Study Objective:

To evaluate the effects of hypothyroidism or rat platelet thromboxane A<sub>2</sub> (TxA<sub>2</sub>) and aortic ring prostacycline by measuring thromboxane B<sub>2</sub> (TxB<sub>2</sub>) and 6-ketoprostaglandin Fl $\alpha$  (6K-PGF $\alpha$ ), respectively, in hypothyroid Sprague-Dawley rats. Second, to determine the effects of treatment on the same parameters with "low and high" dose levothyroxine.

## (16) Technical Approach:

Rats made hypothyroid and controls were sacrificed at various intervals after collecting blood, counting platelets and aggregating platelets. TxB<sub>2</sub> was measured after aggregation by specific RIA segments of aorta were removed, sliced and incubated. Incubate solutions (at various times) were removed for the measurement of 6K-PGF $\alpha$  by RIA. Similar procedures were performed on hypothyroid L-thyroxine treated rats.

## (17) Progress:

During FY85, little more has been accomplished (see FY34 report). We would like to keep protocol active so that minor modifications can be performed via addendums during FY86. More controls and minor technical adjustments will be added.

PRESENTATIONS FOR FY 85 Annual Progress Report

Proto No. 83/117

SERVICE Endocrine

DEPARTMENT Medicine

Sjöberg, R.J., Kidd, G.S., O'Barr, T.P., Wetherill, S., Corby, D., and Hofeldt, F.D.: Thromboxane and Prostacycline Generation in Hypothyroidism. Presented: Eastern Section, APCR, Philadelphia, PA, October 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/119 (3) Status: Completed  
(4) Title: Sarcoidosis: Varying Lymphocyte Concentration in Sequential Bronchoalveolar Lavage

(5) Start Date: March 1983	(6) Est Compl Date: 1985
(7) Principal Investigator: Clarence Hendrix, MAJ, MC	(8) Facility: FAMC

(9) Dept/Svc: Med/Pulmonary	(10) Assoc Investigators: David Thomas, MAJ, MC Talmadge King, M.D.
(11) Key Words: bronchoalveolar lavage sarcoidosis alveolitis	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 10  
d. Total Number of Subjects Enrolled to Date: 10  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To establish the effect, if any, of sequential bronchoalveolar lavage on proportion of lymphocytes recovered.

(16) Technical Approach: The bronchoscope is wedged in a peripheral location and aliquots of saline, 30 ml, injected into a segmental bronchus. Each aliquot is recovered and analyzed. A total of 300 ml are injected. From analysis of each aliquot, correlation between cell population and disease activity will be determined.

(17) Progress: A definite relationship between the amount of saline instilled and the proportion of lymphocytes recovered has been established. Washings with only 30 ml of saline are misleading because of the high proportion of neutrophils isolated. If the first 30 ml aliquot is discarded and the next three aliquots collected more consistent data is collected. Collection lavage fluid in excess of 90 ml has been found to yield little additional information.

Publications: Abstract, ARD; Vol 131 Supplement, A73: 1985

Presentations: Hendrix, C: Bronchoalveolar Lavage Analysis in Sarcoidosis.  
Presented: American College of Physicians Associates Meeting, Denver, CO, March, 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/120 (3) Status: Terminated	
(4) Title: Correlation of Renal Concentrating Ability with Hemoglobin S Concentration in Healthy Military Personnel with Sick Cell Trait: A Clinical Study	
(5) Start Date: 1984	(6) Est Compl Date:
(7) Principal Investigator: John R. Hess, LTC, MC	(8) Facility: FAMC Fitzsimons Army Medical Center
(9) Dept/Svc: Hematology/MED	(10) Assoc Investigators:
(11) Key Words: sickle cell hemoglobin S	Gary Rombert, LTC, MC, USAF Richard Artim, MAJ, MC, USAF
(12) Accumulative MEDCASE:*	
(13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: Sept 84 b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period: 11	
d. Total Number of Subjects Enrolled to Date: 11	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None	

(15) Study Objective: To correlate renal concentrating ability with hemoglobin S concentration in individuals with sickle cell trait in the military age range.

(16) Technical Approach: Patient selection at the United States Air Force Academy with sickle cell trait and normal renal function as documented by a normal urine analysis and a serum creatinine concentration of 1.2 or less at prior screening would be accepted as volunteers for this study after giving informed consent. There are 23 such cadets at this time. Cadets would be instructed to abstain from drinking water after 1900 hours the day before the study and to report at 0700 hours to the study area. Hourly urine samples would be collected for six samples and measured for osmolality and urine volume and two blood samples would be drawn one at the beginning and one at the end of the urine collection period and measured for osmolality and electrolytes, glucose, BUN and creatinine. The six osmolalities and volumes for each individual would be plotted to see that they approach a maximum concentration ability.

(17) Progress: Eleven patients have been entered in the study thus far with no problems encountered. Cadets are no longer to be studied, Terminate.

Publications and Presentations: Presented at Army Heme/Onc Meeting, Letterman AMC, Oct 84.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/121 (3) Status: Ongoing  
(4) Title: Expiratory Spirometry/Lung Compartment Ratios for Assessment of Pulmonary Impairment

(5) Start Date: Aug 83	(6) Est Compl Date: April 1986
(7) Principal Investigator: John D. Olsen, CPT, MC	(8) Facility: FAMC

(9) Dept/Svc: Pulmonary/DOM	(10) Assoc Investigators: Michael E. Perry, COL, MC
(11) Key Words: spirometry ratios	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 1984 b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 10  
d. Total Number of Subjects Enrolled to Date: 36  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: Define normal ratios for FEV<sub>1</sub>/TLC; FEV<sub>1</sub>/RV; FEV<sub>1</sub>/FRC. Determine if these simple ratios are a better mediator of obstructive lung impairment than the FEV<sub>1</sub>/FVC.

(16) Technical Approach: An estimated 100 subjects to be enrolled and will undergo routine spirometry, body plethysmography and a minimal exertion on a treadmill at 0 grade and 2 mph for 4 min measuring minute ventilation ratios will be generated from this data and statistically analyzed.

(17) Progress: An additional 10 subjects have been studied using state I exercise and this number is too small for statistical analysis.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/122 (3) Status: ongoing  
(4) Title: The role of food allergy in the pathogenesis of migraine headaches.

(5) Start Date: Sep 83	(6) Est Compl Date: June 86
(7) Principal Investigator: HS Nelson, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MED/Allergy	(10) Assoc Investigators:
(11) Key Words: migraine headache food allergy prostaglandins	W. Stafford, MAJ, MC TR Vaughan, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 34  
d. Total Number of Subjects Enrolled to Date: 60  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

not applicable

(15) Study Objective: In this study the value of skin testing to a battery of food allergens will be determined in directing therapy and defining a diet which will cause a decreased frequency of migraine headaches in affected patients.

(16) In this study, approx. 100 patients will be randomly referred from the Neurology Clinic who have at least 3 migraine headaches a month. Those patients will on a reg. diet, keep dietary records and be taken off any chronic medications over a 30-day period. They will then undergo skin testing to 83 common foods and be placed on an allergy elimination diet for 30 days. If there is a reduction in the frequency of headaches, they will undergo an open challenge and if that is positive, they will undergo double-blind challenges.

(17) Progress: At the present time 60 people have been enrolled in the study. Eight have completed the full study including double-blind challenges.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/123 (3) Status: Ongoing	
(4) Title: IN VITRO TESTING OF CRYOPRESERVED PARATHYROID TISSUE: FUNCTIONAL VIABILITY AND REPLICATIVE CAPACITY AFTER USING A "SIMPLIFIED" FREEZING TECHNIQUE	
(5) Start Date: October 1983	(6) Est Compl Date: October 1987
(7) Principal Investigator: Gerald S. Kidd, LTC, MC Albert McCullen, CPT, VC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators:
(11) Key Words: cryopreserved parathyroid	Don Mercill, DAC Les Kramer, SP5
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period: N/A	
d. Total Number of Subjects Enrolled to Date: N/A	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A	

(15) Study Objective: Dog parathyroid tissue will be cryopreserved for various intervals using a "simplified" freezing technique which does not require a programmed freezer. The tissue is placed in tissue culture medium, 4°C, for two hours. The tissue is then transferred to chilled vials containing tissue culture medium, autologous serum, and DMSO and immediately placed in a freezer at -80°C. After 16 hours, the vials are directly transferred to a liquid nitrogen container for storage. Successful demonstration of adequate parathyroid function after cryopreservation will be the basis for attempting parathyroid autotransplantation of cryopreserved tissue in humans at our institution as well as a more general application at those institutions where only a "simplified" freezing technique could be accomplished.

(16) Technical Approach: Thawed tissue will be compared to fresh tissue using in vitro studies that measure functional viability and replicative capacity. Functional viability will be assessed by measuring the suppressibility of PTH from dispersed parathyroid cells in suspension when the calcium concentration in the solution is changed. Replicative capacity is the ability of a cell to incorporate nutrient materials for cell survival and replication will be assessed by measuring DNA, RNA and protein synthesis in the cryopreserved specimens.

(17) Progress: We have been able to isolate and remove parathyroid glands from a large dog without difficulty and have been able to run assays of PTH from both fresh and frozen specimens from one dog. The only problem encountered is cell suspension technique needs refinement. The major principal investigator (CPT Collazo) has departed FAMC. However, would like to keep active for new Endocrine Fellowship in FY86.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:83-124 (3) Status: Terminated

(4) Title: A Prespective Evaluation of Esophageal Changes and Patients Undergoing Esophageal Radiation

(5) Start Date: 27 Apr 84

(6) Est Compl Date: 31 Dec 85

(7) Principal Investigator:

(8) Facility: FAMC

Frank Moses, MAJ, MC

(9) Dept/Svc: Gastroenterology

(10) Assoc Investigators:

(11) Key Words: Radiation Esophagitis

M. Herwitz, MAJ, MC  
Peter Blue, LTC, MC  
R. Claypool, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

To determine changes prospectively in structure and function of the esophagus while undergoing radiation as an innocent bystander by means of standardized questionnaire, upper panendoscopy with viral and fungal culture, esophageal radionuclide scan, 24 hour pH monitor and esophageal motility.

(16) Technical Approach:

Patients entered into \_\_\_\_\_ protocol undergo the above listed tests in standard medical fashion at inception of radiation, 4 weeks into radiation, and 4 months after start of radiation.

(17) Progress:

Since the start of the protocol at the date as listed above, two patients have been entered into the protocol. During the above reporting period zero patients have been into the protocol. No eligible patients have been referred for consideration within the reported period. Due to this fact, no further work will be performed under this protocol and the status will be terminated. No publications or presentations have arisen from this protocol.

# DETAIL SUMMARY SHEET

(Ref: HSCR 40-23 &  
HSPA-I Ltr,  
8 July 1982

(1) Date: FY 85 (2) Protocol WU Nr.: 83/125 (3) Status: Completed  
(4) Title: Carbon Dioxide Retention with PEEP during High Frequency Jet Ventilation

(5) Start Date: May 1984 (6) Est Compl Date: Completed  
(7) Principal Investigator (8) Facility: FAMC  
Keith Wolfe, CAPT, MC  
Michael Perry, COL, MC

(9) Dept/Svc: Medicine/Pulmonary (10) Assoc Investigators:  
(11) Key Words:  
Dead Space  
High Frequency Ventilation  
Carbon Dioxide

(12) Accumulate MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of subjects enrolled during reporting period: 12 Animals  
d. Total number of subjects enrolled to date: 12 Animals  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND.:

(Continue on a separate sheet, designating this continuation as (14)e.)

(15) Study Objective: To ascertain if changes in CO<sub>2</sub> retention during high frequency jet ventilation are due solely to changes in tidal volume or whether some other factor, such as dead space, may be a factor.

(16) Technical Approach: Animals were studied at a constant frequency and I:E ratio, while varying the driving pressure to maintain a constant Tidal volume. Increases in CPAP (or PEEP) were made and the corresponding changes in CO<sub>2</sub> retention observed. Effects of changes in cardiac output on CO<sub>2</sub> were also studied by (cont)

(17) Progress: A definite relationship between CPAP and CO<sub>2</sub> retention, independent of tidal volume was established at frequencies of 200/min. The time course of CO<sub>2</sub> retention was surprising, and it usually required at least an hour for this to fully develop. No relationship between cardiac output and CO<sub>2</sub> retention was observed. We attribute CO<sub>2</sub> retention to CPAP-induced changes in functional dead space.

- (16) Technical Approach: (cont) volume loading the animals after CO<sub>2</sub> retention developed.

PRESENTATIONS: Wolfe, G.K., Perry, M.E.: CPAP-Induced Carbon Dioxide Retention During High Frequency Jet Ventilation. Presented: Carl W. Tempel Pulmonary Disease Symposium, San Francisco, CA, October 1984.

PUBLICATIONS: In progress.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/126 (3) Status: Ongoing	
(4) Title: THE ROLE OF ALTERED PROSTAGLANDIN SYNTHESIS IN THE IMPAIRED WATER EXCRETION AND ABNORMAL RENIN-ALDOSTERONE AXIS OF HYPOTHYROIDISM	
(5) Start Date: August 1983	(6) Est Compl Date: August 1987
(7) Principal Investigator: Robert J. Sjoberg, CPT, MC Gerald S. Kidd, LTC, MC Thomas P. O'Barr, Ph.D., DAC Fred D. Hofeldt, COL, MC (Ret)	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators:
(11) Key Words: prostaglandin synthesis water metabolism hypothyroidism	None.
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period: 0	
d. Total Number of Subjects Enrolled to Date: 0	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	

(15) Study Objective: The objective of this study is to determine in an indirect manner, i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: No patients have been entered in this study during the past year because of conflicting priorities in our unit. However, we anticipate studying five patients during the coming fiscal year.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/127 (3) Status: ongoing

(4) Title:

Double-blind controlled trial of individually polymerized grass pollens in the treatment of seasonal allergic rhinitis..

(5) Start Date: 1984

(6) Est Compl Date: 1985

(7) Principal Investigator:  
HS Nelson, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Assoc Investigators:

(11) Key Words:  
polymerized extract  
allergy immunotherapy

EW Bantz, MAJ, MC  
RW Weber, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 43

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

none

(15) Study Objective: To assess the relative effect of immunotherapy with polymerized grass on the immediate and late cutaneous reactions to grass extract. To determine the clinical and immunologic response to booster injections of polymerized grass.

(16) Technical Approach: Patients received over a period of 8 wks 11 injections of polymerized grass extract or of a placebo containing histamine and caramelized sugar. The immunologic response is measured by titrated skin test, specific IgE and specific IgG performed before and after immunotherapy. Symptom scores are collected through the grass pollen season. Patients who received placebo during the initial immunotherapy period were offered the opportunity to receive the active extract with titrated skin tests before and after to assess the impact of the immunotherapy on the immediate and late cutaneous reaction. It is hoped that in the spring of 1986 to be able to offer booster injections to those individuals still residing in the area who participated in the original study.

(17) Progress: Forty-three patients were randomized to placebo or active immunotherapy in the grass pollen season of 1984. This portion of the study is now complete. Those patients who received placebo injections prior to the 1984 season in most cases elected to receive active immunization during early 1985 and titrated skin tests were performed before and following this course of immunotherapy. It is hoped that arrangements can be completed with the company providing the extract to offer booster injections prior to the 1986 season. If this is done, there will be an immunologic assessment both by skin tests, RAST and blocking antibody as well as collection of symptom scores during the grass season of 1986.

PRESENTATIONS FOR FY 85 Annual Progress Report

Proto No. 83/127

SERVICE Allergy

DEPARTMENT med

Miller BT; Double-blind study of immunotherapy with polymerized grass.  
Presented at the 37th annual FAMC Symposium 23-25 Jan 85.

Miller BT: Comparison of standardized quantitative skin test assay and RAST inhibition for assessment of extract potency. Presented 37th annual FAMC Symposium 23-25 Jan 85

Miller BT, Brown JS, Moyer DB, Weber RW, Nelson HS: Double-blind controlled trial of polymerized grass pollens in the treatment of seasonal allergic rhinitis. Presented 41st annual Congress of Am. College of Allergists, 2-6 Feb 85, Bal Harbour FL.

Miller BT, Ledoux RA, Brown JS, Nelson HS: Comparison of standardized quantitative skin tests assay and RAST inhibition for assessment of extract potency. Presented 41st annual Congress Amer. College of Allergists, Bal Harbour, FL, 2-6 Feb 85.

Publications: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/100 (3) Status: Ongoing

(4) Title: THE EFFECT OF ABNORMAL THYROID STATES ON THE METABOLISM OF THEOPHYLLINE AND METHYLPREDNISOLONE

(5) Start Date: Feb 84

(6) Est Compl Date: Jul 87

(7) Principal Investigator:  
Michael T. McDermott, MAJ, MC  
Ray Vaughan, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:

(11) Key Words:  
theophylline  
methylprednisolone  
hyperthyroidism  
hypothyroidism

Stanley J. Szeffler, MAJ, MC  
Harold S. Nelson, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 84 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 3

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

To study the effects of hyperthyroidism and hypothyroidism on the metabolism of theophylline and methylprednisolone.

(16) Technical Approach:

Consenting hyperthyroid and hypothyroid patients will have a 12-hour intravenous infusion of theophylline or methylprednisolone, or both, (on separate days), and hourly blood levels measured. The study will be done while thyroid function is abnormal and will be repeated when thyroid function is normal.

(17) Progress:

Three patients have been studied while hyperthyroid or hypothyroid, but have not yet been restudied when euthyroid.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/101 (3) Status: Ongoing  
 (4) Title: Antibiotic Therapy of Acute Exacerbations of Chronic Bronchitis  
 A controlled study using TMP/SMX

(5) Start Date: Sept 84	(6) Est Compl Date: Dec 86
(7) Principal Investigator: Richard Kucera Cpt, MC	(8) Facility: FAMC

(9) Dept/Svc: Medicine/Pulmonary	(10) Assoc Investigators:
(11) Key Words: Trimethaprim/Sulfamethoxazole Chronic Bronchitis	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period: 7  
 d. Total Number of Subjects Enrolled to Date: 7  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

This double-blind study was undertaken in an attempt to clarify whether a specific therapeutically useful antibiotic plays a significant role in acute exacerbations of chronic bronchitis. The drug to be used is TMP/SMX. The patient population will include patients with documented moderate to severe bronchitis by clinical symptoms and pulmonary function tests who have acute exacerbations of their symptoms.

(16) Technical approach: Patients admitted with worsening pulmonary symptoms, who have no documented allergy to TMP/SMX undergo a battery of tests as a baseline and a patient questionnaire and physical exam and CXR. These are repeated on day 4 & 7 to see if there has been any improvement. On day 1 the patient is placed blindly on either a placebo or the study drug, and kept on it for seven days.

(17) Seven patients have been entered in to the study to date (fiscal year 85), and since the drug is unknown to the authors, it is not known whether the benefit seen is due to antibiotic or placebo.

Publications and presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85		(2) Protocol WU#: 84/102		(3) Status: Ongoing	
(4) Title: DEVELOPMENT OF A RADIOIMMUNOASSAY FOR GASTRIC INHIBITORY POLYPEPTIDES (GIP)					
(5) Start Date: Feb 84			(6) Est Compl Date: Feb 86		
(7) Principal Investigator: Michael T. McDermott, MAJ, MC			(8) Facility: FAMC		
(9) Dept/Svc: Medicine/Endocrine			(10) Assoc Investigators:		
(11) Key Words: radioimmunoassay gastric inhibitory polypeptide (GIP)			Gerald S. Kidd, LTC, MC		
(12) Accumulative MEDCASE:*			(13) Est Accum OMA Cost:*		
*Refer to Unit Summary Sheet of this report.					
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____					
c. Number of Subjects Enrolled During Reporting Period: _____					
d. Total Number of Subjects Enrolled to Date: _____					
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").					

N/A

- (15) Study Objective:  
To develop a radioimmunoassay to measure GIP.
- (16) Technical Approach:  
A RIA for GIP will be developed using established RIA techniques after purchase of GIP antibodies and purified GIP.
- (17) Progress:  
GIP antibodies and purified GIP have been obtained but thus far there has been difficulty iodinating the GIP. This will require further work.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/103 (3) Status: Ongoing  
(4) Title: GASTRIC INHIBITORY POLYPEPTIDE (GIP) IN VARIOUS DISORDERS OF CARBOHYDRATE METABOLISM

(5) Start Date: Feb 84	(6) Est Compl Date: Feb 88
(7) Principal Investigator: Michael T. McDermott, MAJ, MC	(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators:
(11) Key Words: gastric inhibitory polypeptide (GIP) hypoglycemia diabetes mellitus	Gerald S. Kidd, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:  
To measure GIP in states of altered carbohydrate metabolism such as diabetes mellitus and reactive hypoglycemia.

(16) Technical Approach:  
Multiple serum samples on patients with diabetes mellitus and reactive hypoglycemia have been collected and stored according to previously approved protocols. In this study, we will use this stored serum to measure GIP.

(17) Progress:  
No progress as of yet because the GIP RIA is still in the process of being established.

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/106 (3) Status: Ongoing

(4) Title:

RESPIRATORY PATTERNS IN HYPOGONADAL PATIENTS

(5) Start Date: Feb 84

(6) Est Compl Date: Feb 86

(7) Principal Investigator:

(8) Facility: FAMC

Michael T. McDermott, MAJ, MC

Brenda K. Schneider, MD  
Pulmonary Fellow, UCHSC

(9) Dept/Svc:

(10) Assoc Investigators:

(11) Key Words:

hypogonadism  
testosterone  
sleep apnea

Gerald S. Kidd, LTC, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Sep 84 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 13

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

To study the effect of sex hormones, testosterone and estrogen on respiratory patterns and sleep apnea.

(16) Technical Approach:

Patients undergo hypoxic and hypercapnic ventilatory drive studies by measuring tidal volume and respiratory rate while breathing various concentrations of oxygen and carbon dioxide and then undergo sleep studies under observation for the presence and frequency of sleep apnea. These studies are done in hypogonadal males 4 days and 4 weeks after shots of depot testosterone, and in postmenopausal females while on and after 4 weeks off Premarin and also once in hirsute females, who are compared with established normal controls.

(17) Progress:

Seven men have completed the study. There is one publication (in press) and a second manuscript has been submitted. Two women have completed the study and one other has completed the first part.

PUBLICATIONS for FY 85 Annual Progress Report

Proto No. 84/106

SERVICE Endocrine

DEPARTMENT Medicine

- (1) White, D.P., Schneider, B.K., Santen, R.J., McDermott, M.T., et al: The Influence of Testosterone on Ventilation and Chemosensitivity in Men. J. Applied Physiol. (In Press).
- (2) Schneider, B.K., Pickett, C.K., McDermott, M.T., et al: The Influence of Testosterone on Breathing During Sleep. (Submitted).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/107 (3) Status: Completed  
(4) Title: SURVEY OF ASPERGILLUS CONTAMINATION OF THE ENVIRONMENT DURING HOSPITAL  
RENOVATION: AND, THE EFFICACY OF INFECTION CONTROL MEASURES IN PREVENTING  
NOSOCOMIAL ASPERGILLOSIS

(5) Start Date: December 1983 (6) Est Compl Date: November 1984  
(7) Principal Investigator: (8) Facility: FAMC

Steven M. Opal, MD

(9) Dept/Svc: Medicine/Inf. Disease (10) Assoc Investigators:  
(11) Key Words: Arnold A. Asp, CPT, MC. Preston B.  
Aspergillus infection Cannady, COL, MC. Pari L. Morse, GS-9,  
Nosocomial infection Clinical Microbiologist, DCI. Linda J. Burton,  
MAJ, ANC. Philip Hammer, SP5, Infection  
Control Service

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: Not applicable  
d. Total Number of Subjects Enrolled to Date: Not applicable  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective of this study is to determine the efficacy of Infection Control measures in preventing the spread of Aspergillus infections during hospital construction at FAMC. This institution has experienced a significant outbreak of nosocomial aspergillosis associated with hospital construction on the 4th floor. Construction is ongoing on the third floor and attempts have been made by the Infection Control Service to prevent similar episodes of invasive aspergillosis associated with this construction project.

(16) Technical Approach:

By the use of physical barriers, external venting, high efficiency filters, and Copper-8-quinolinolate treatments, the incidence of nosocomial aspergillosis has decreased to no cases during the Infection Control project. A sampling of the hospital air has demonstrated a significant decrease in the amount of Aspergillus spores generated in patient care areas following the institution of Infection Control measures.

(17) Progress:

There was a reduction in viable spores from 4.2 spores/m<sup>3</sup> air to 0.008 spores/m<sup>3</sup> air after all three control measures were enforced. There have been no further cases of disseminated Aspergillus since implementation of infection control.

PRESENTATIONS FOR FY 85 Annual Progress Report

Proto No. 84/107

SERVICE Infectious Disease

DEPARTMENT Medicine

- (1) Opal, S.M.: Survey of Aspergillus Contamination of the Environment During Hospital Renovation; and, The Efficacy of Infection Control Measures in Preventing Nosocomial Aspergillosis. Presented: 85th Annual Meeting of American Society for Microbiology, Las Vegas, NV, 3-7 March 1985.
- (2) Asp, A.A.: Survey of Aspergillus Contamination of the Environment During Hospital Renovation; and, The Efficacy of Infection Control Measures in Preventing Nosocomial Aspergillosis. Presented: Associate's Meeting of American College of Physicians, Denver, CO, March 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/108 (3) Status: Ongoing  
 (4) Title: The effect of ultraviolet light (UVB) on the production of prostacyclin (PGI<sub>2</sub>) by cultured human microvasculature endothelial cells.

(5) Start Date: 15 Dec 1983 (6) Est Compl Date: 30 Dec 1986  
 (7) Principal Investigator: James Fitzpatrick MD Major, MC (8) Facility: FAMC

(9) Dept/Svc: DOM/Derm (10) Assoc Investigators:  
 (11) Key Words: UVB, Endothelial cells, prostacyclin  
 Thomas P. O'Barr PhD, DAC  
 Ellen Swanson DAC  
 Don Merrell DAC  
 Chuck Ferris PhD, Capt, MSC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results: N/A  
 c. Number of Subjects Enrolled During Reporting Period: N/A  
 d. Total Number of Subjects Enrolled to Date: N/A  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine if UVB i physiologic doses will stimulate the release of prostacyclin from human endothelial cells.

(16) Technical approach: Endothelial cells will be cultured from adipose tissue and irradiated with various doses of UVB and PGI<sub>2</sub> will be assayed by a RIA.

(17) Progress: Preliminary results have shown an increase of prostacyclin when endothelial cells are irradiated with physiologic levels of UVB. Beginning in Jan 1986 the studies will be repeated with a slight modification in the type of measurements used to measure the total numbers of cell in culture. In the past we had used a fluorescent test which measured total cell DNA and we will be changing to a method of directly counting the numbers of cells. Since it has become apparent that the UVB directly suppresses the production of DNA, we feel we can no longer use this method.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/109 (3) Status: Completed	
(4) Title: Two Dimensional Echocardiographic Evaluation of Exercise-Induced Wall Motion Abnormalities: Detection of Coronary Artery Disease	
(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: William D. Bowden, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Med/Cardiology	(10) Assoc Investigators:
(11) Key Words: exercise echo ischemic heart disease	H. Thomas, Jr., COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: 13	
d. Total Number of Subjects Enrolled to Date: 19	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

(15) Study Objective: To evaluate the value of two dimensional (2-D) echocardiographic analysis of exercise induced left ventricle wall motion abnormalities in the evaluation of patients with suspected ischemic heart disease. Pre and post exercise 2-D echocardiograms will be analyzed to identify exercise induced left ventricular wall motion abnormalities. These studies will be correlated with ST segment changes noted during exercise stress testing and to the findings at coronary cineangiography.

(16) Technical Approach: Twenty-five patients referred to FAMC for cardiac catheterization without evidence of a prior myocardial infarction will be enrolled in the study. The usual work up of these patients will be modified to include a 2-D echocardiogram at rest and after completing a treadmill stress test. The echocardiogram will be analyzed for changes in left ventricular wall motion that occur during exercise suggesting regional ischemic changes. These changes will be correlated with the data found at coronary cineangiography.

(17) Progress: Ninetten patients referred to FAMC for possible cardiac catheterization underwent exercise stress testing with the addition of 2-D echocardiography. No patient had ECG evidence for prior myocardial infarction or known cardiomyopathy. A graded exercise stress test was obtained with the addition of a resting, immediately post and three minutes post exercise apical two and four chamber 2-D echocardiogram. The left ventricle was analyzed for segmental wall motion abnormalities in a blinded fashion. The exercise stress test was evaluated

## Progress - continued

by a separate observer. Eighteen patients underwent cardiac catheterization. The sensitivity and specificity for exercise stress testing was 67% and 57% while echocardiography was 50% and 86% respectively. The combined technique of exercise echocardiography improved the sensitivity to 83% and the specificity of 57%. This suggests that a simplified 2-D exercise echocardiogram can increase the sensitivity without changing the specificity of a screening exercise stress test.

Publications: None

## Presentations:

Bowden, William D: Two Dimensional Echocardiographic Evaluation of Exercise-Induced Wall Motion Abnormalities: Detection of Coronary Artery Disease. Presented: 14th Annual Scientific Session, William Beaumont Army Medical Center, El Paso, TX, May 1985.

- (1) Date: 30 Sep 84 (2) Protocol WU#: 84/110 (3) Status: Ongoing  
 (4) Title: Survey of the extrachromosomal elements of Campylobacter species obtained from environmental and clinical isolates.
- (5) Start Date: May 1984 (6) Est. Compl Date: December 1986  
 (7) Principal Investigator:  
 Steven M. Opal, MD, MAJ, MC (8) Facility: FAMC  
 Martin Blazer, MD, C, Inf Dis  
 Service, VA Hospital
- (9) Dept/Svc: Medicine/Infec. Disease (10) Assoc Investigators  
 (11) Key Words: Pari Morse, GS-9,  
Campylobacter; virulence factors; Clinical Microbiologist, DC  
plasmids
- (12) Accumulative MEDCASE\* (13) Est Accum OMA Cost\*  
 \*Refer to Unit Summary Sheet of this report
- (14) a. Date, Latest HUC Review: none b. Review Results: NA  
 c. Number of Subjects Enrolled During Reporting Period: NA  
 d. Total Number of Subjects Enrolled to Date: NA  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on separate sheet, and designated as "(14)e".)
- (15) Study Objective:  
 The objective of this investigation is to study the extrachromosomal elements of Campylobacter species to determine their contribution to the virulence of these organisms. It has previously been demonstrated that virulence plasmids are present in virtually all the Enterobacteriaceae. These plasmids contribute to the resistance to the bacteriocidal effect of human serum. Campylobacter species C. fetus are uniformly serum resistant owing to a smooth LPS. Campylobacter jejuni are generally serum sensitive owing to rough LPS.
- (16) Technical Approach:  
 The majority of C. fetus strains which are serum resistant have been found to have a 34 M dal. plasmid. Serum sensitive derivatives invariably lack this extrachromosomal element. The current work requires further characterization of this plasmid by restriction endonuclease digestion.
- (17) Restriction endonucleases EcoRI and HindIII will be used to digest common plasmids of serum resistant C. fetus strains from geographically separate sources to determine their molecular identity.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/111 (3) Status: Completed

(4) Title: Incidence of Bacteremia following Transbronchial Needle Aspiration and Fiberoptic Bronchoscopy

(5) Start Date: 1984

(6) Est Compl Date: 1985

(7) Principal Investigator:  
Michael Witte, MAJ, MC  
Jimmy Gilbert, M.D.  
Steven Opal, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Med/Pulmonary

(10) Assoc Investigators:

(11) Key Words:

bacteremia

bronchoscopy

transbronchial needle aspiration

endocarditis prophylaxis

Jerry Pluss, M.D.

Michael Perry, M.D.

John Olsen, M.D.

David Thomas, M.D.

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 50

d. Total Number of Subjects Enrolled to Date: 50

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective: To determine incidence of fever and bacteremia following TBNA for cardcarditis prophylaxis purposes.

(16) Technical Approach: Blood cultures 5 min and 30 min after TBNA and anytime of fever in the subsequent 24 hours.

(17) Progress: No incidence of bacteremia (total 120 blood cultures) 10% incidence of fever.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/112 (3) Status: Terminated

(4) Title: Congestive Heart Failure and Proteinuria

(5) Start Date: 1984 (6) Est Compl Date: Terminate

(7) Principal Investigator:  
J. Hasbargen, M.D.  
R. Kucera, M.D.

(8) Facility: FAMC

(9) Dept/Svc: Med/Nephrology

(10) Assoc Investigators:

(11) Key Words:  
congestive heart failure  
proteinuria

(12) Accumulative MEDCASE: \* (13) Est Accum OMA Cost: \*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results: 0  
c. Number of Subjects Enrolled During Reporting Period: 0  
d. Total Number of Subjects Enrolled to Date: 0  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective:  
To determine the incidence of proteinuria in congestive heart failure.

(16) Technical Approach: Random urinalysis, analyzed for creatinine and protein.

(17) Progress: Terminated secondary to principal investigator's time constraints

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/113 (3) Status: Completed	
(4) Title: Functional Assay to Determine Shelflife of Methacholine and Atropine Methylnitrate Solutions	
(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: William R. Tipton, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Med/Allergy	(10) Assoc Investigators: Robert Ledoux
(11) Key Words: atropine methonitrate methacholine shelflife	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
1. Number of Subjects Enrolled During Reporting Period:	
2. Total Number of Subjects Enrolled to Date: -	
c. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA	

(15) Study Objective: To determine the shelflife of reconstituted atropine methonitrate and methacholine.

(16) Technical Approach: Reconstitute atropine methonitrate and methacholine from the powdered form into solutions at intervals, then compare the effect of these solutions of various ages to freshly reconstituted material employing contraction and relaxation of a guinea pig tracheal ring preparation.

(17) Progress: Completed

Publications:

WR Tipton, RA Ledoux. Functional Shelflife of Methacholine and Atropine Methonitrate Solutions. (Abst) Ann Allergy 54:347;1985.

Presentations:

WR Tipton. Functional Shelflife of Methacholine and Atropine Methonitrate Solutions. Presented: 41st Annual Congress, The American College of Allergists, Bal Harbour, FL, 3 February 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/114 (3) Status: Terminated  
(4) Title: The Relative Development of Subsensitivity to the Bronchodilator and Musculoskeletal Side Effects of beta-2 Adrenergic Agonists.

(5) Start Date: 1984 (6) Est Compl Date: 1986

(7) Principal Investigator: Harold S. Nelson, COL, MC  
(8) Facility: FAMC

(9) Dept/Svc: Allergy/MED

(11) Key Words:  
beta adrenergic agonists  
side effects

(10) Assoc Investigators:

R.W. Weber, COL, MC  
E.W. Bantz, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 3

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine whether tolerance develops to an equal degree to the side effects and bronchodilator action of beta adrenergic agonists.

(16) Technical Approach: The bronchodilating and tremor-inducing effect of two doses of albuterol and terbutaline would be determined. These will be measured before and following a 2-wk period of administration of these drugs. The two drugs then will be compared with regard to their ratio of tremor to bronchodilatation and also to the development of tolerance to tremor vs. that of bronchodilatation.

(17) Progress: Two patients have completed the study, one is enrolled. Due to a difficulty in recruitment of patients, the protocol has been submitted for approval at the Wilford Hall USAF Medical Center, and it is anticipated that a number of patients will be studied at that facility.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/115 (3) Status: Ongoing  
 (4) Title: Heterotransplantation of Basal Cell Carcinomas to Nude Mice

(5) Start Date: 1984	(6) Est Compl Date: July 1986
(7) Principal Investigator: Charles F. Ferris, Ph.D. CPT, MS	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators:
(11) Key Words: basal cell carcinoma heterotransplantation nude mice	R.E. Grimwood, M.D. J. Clark Huff, M.D.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in-vivo model of human basal cell carcinoma in the athymic mouse.

(16) Technical Approach: Basal cell carcinoma tissue obtained from excess tissue obtained from Moh's surgery is transplanted to a subcutaneous pocket created by a linear incision on the abdomen of the nude mouse. The mouse will have been splenectomized and transplantation is followed by weekly intraperitoneal injections of antilymphocyte serum. Tumor weight is taken before implantation and measurements of tumor size taken at weekly intervals. Autoradiography and immunofluorescent studies are performed at the time of tumor harvest as well as routine histology and tumor weight.

(17) Progress: To date we have successfully transplanted 35+ tumors which maintain the histology and protein products of the originally transplanted tumor. We are now actively defining the growth parameters of these tumors but have not completed data yet. We have established the proliferating area of the tumor.

## PUBLICATIONS:

1. Grimwood RE, Harbel J, Clark RAF: Fibronectin in Basal Cell Epitheliomas: Sources and Significance. Journal of Investigative Derm 82: 145-149, 1984
2. Grimwood RE, Johnson CA, Ferris CF, Mercill DB, Mellette JR, Huff JC: Transplantation of Human Basal Cell Carcinomas in Athymic Mice. Cancer
3. Ferris, CF, Grimwood RE, Kramer LC, Mercill DB and Huff JC: The proliferating cells of a human basal cell carcinoma are the peripheral pallisaded cells. Abst. Clinical Research
4. Grimwood RE, Ferris CF, Mercill DB and Huff JC: The proliferating cells of human basal cell carcinoma are located on the periphery of tumor nodules. J. Investigative Derm. In Review

## PRESENTATIONS:

1. Grimwood RE, Johnson CA, Kramer LC, Mercill DB and Huff JC: Heterotransplantation of Human Basal Cell Epitheliomas in Nude Mice. Presented: SID Meeting, Washington, DC, May 1984.
2. Grimwood RE, Ferris CF, Nielsen LE, Huff JC, Clark RAF: Basal Cell Carcinomas Grown in Nude Mice Produce and Deposit Fibronectin in the Extracellular Matrix. Presented: SID meeting, Washington, DC, May 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85		(2) Protocol WU#: 84/117		(3) Status: Ongoing	
(4) Title: ARTERIAL AND RENAL PRODUCTION OF PROSTAGLANDINS IN VARIOUS STEROID EXCESS STATES					
(5) Start Date: July 1984			(6) Est Compl Date: July 1986		
(7) Principal Investigator: Gerald S. Kidd, LTC, MC			(8) Facility: FAMC		
(9) Dept/Svc: Medicine/Endocrine			(10) Assoc Investigators:		
(11) Key Words: prostaglandins rats steroids			T. P. O'Barr, Ph.D. Ellen Swanson, MS Michael T. McDermott, MAJ, MC Tony L. Walden, CPT, MC Donald Corby, COL, MC		
(12) Accumulative MEDCASE:*			(13) Est Accum OMA Cost:*		
*Refer to Unit Summary Sheet of this report.					
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____					
c. Number of Subjects Enrolled During Reporting Period: N/A					
d. Total Number of Subjects Enrolled to Date: Animal Study					
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A					
(15) Study Objective: To determine the effects of various steroids on rat renal, arterial and platelet prostaglandin production. Steroids include pure glucocorticoids, mineralocorticoids and NaCl and ACTH induced steroid.					
(16) Technical Approach: Animals are treated in vivo with above agents then sacrificed. In vitro production of platelet $TxB_2$ , aortic 6-ketoPGF $1\alpha$ and renal medullary PgE $_2$ are measured by RIA. These assays are compared with controls.					
(17) Progress: The majority of the study is completed and has been presented in abstract form, however, more controls may need to be studied with NaCl supplementation.					

SERVICE Endocrine

DEPARTMENT Medicine

Sjoberg, R., Swanson, E., O'Barr, T., Walden, T.L., and Kidd, G.S.:  
Influences of Methylprednisolone and Desoxycorticosterone With Salt-Loading on  
the Ability of Arterial and Renal Tissue to Produce Prostaglandins. (Abst.)  
Endocrinology 116 (Supp 1)(A-916), 229, 1985.

**Presentations:**

Sjoberg, R., Swanson, E., O'Barr, T., Walden, T.L., and Kidd, G.S.:  
Influences of Methylprednisolone and Desoxycorticosterone with Salt-Loading  
on the Ability of Arterial and Renal Tissue to Produce Prostaglandins.  
Presented: 67th Annual Meeting of the Endocrine Society, Baltimore, MD.  
June 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/118 (3) Status: Terminated

(4) Title:

Evaluation of the Role of Tension in Chemotherapy Induced Nausea and Vomiting

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

Major Kenneth Beougher

(9) Dept/Svc:

(10) Assoc Investigators:

(11) Key Words:

Major James Wilson

Major Arlene Zaloznik

Elizabeth Rahdert

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16)

(17) Progress: No patients were registered in the study as the Principal Investigators both Major Beougher and Major Wilson did not begin the study.

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/119 (3) Status: Ongoing

(4) Title: TREATMENT OF GRAVES' OPTHALMOPATHY WITH CYCLOSPORIN

(5) Start Date: 30 Oct 84

(6) Est Compl Date: Oct 87

(7) Principal Investigator:

(8) Facility: FAMC

Michael T. McDermott, MAJ, MC

WRAMC

Leonard Wartofsky, COL, MC

MAMC

BAMC

(9) Dept/Svc: Medicine/Endocrine

(10) Assoc Investigators:

(11) Key Words:

Anthony Truxal, CPT, MC

ophthalmopathy  
cyclosporin  
prednisone

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 2

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

None.

(15) Study Objective:

To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach:

Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and  $\beta$ -2 microglobulin (urine).

(17) Progress:

Two patients have been studied at FAMC. Neither improved on cyclosporine or prednisone. No toxicity noted. No patients have been studied from the other centers.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/120 (3) Status: ongoing  
 (4) Title: The effect of chronic administration of antihistamines on skin test suppression and rate of metabolism.

(5) Start Date: 1984	(6) Est Compl Date: 1985
(7) Principal Investigator: HS Nelson, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MED/Allergy	(10) Assoc Investigators:
(11) Key Words: antihistamines subsensitvity metabolism	W Dolen, MAJ, MC EW Bantz, MAJ, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period: 14	
d. Total Number of Subjects Enrolled to Date: 14	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	

none

(15) Study Objective: To examine the development of subsensitivity to anti-H-1 effects of chlorpheniramine and to determine whether the tolerance results from enhanced metabolism or decreased function.

(16) Technical Approach: Patients have titrated prick tests performed with histamine and 48:80 or an allergen to which they are sensitive. They are then placed on chlorpheniramine for 3 days and the skin tests are repeated. Chlorpheniramine is then stopped and skin tests are repeated daily while blood is obtained for chlorpheniramine levels. After a washout period the same process is repeated; however, chlorpheniramine is administered for 21 days the second round. The purpose is to study the suppressive effect of chlorpheniramine at 3 days and the plasma chlorpheniramine level and clearance and the same parameters at 21 days.

(17) Progress: All 14 patients contemplated have completed the study which now awaits only the performance of the chlorpheniramine blood levels by the Clinical Investigation Service.

Presentations and publications none.

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/121 (3) Status: Completed  
 (4) Title: THE EFFECT OF ANDROGENS AND ESTROGENS ON ARACHIDONIC ACID METABOLITES

(5) Start Date: 7 Dec 84	(6) Est Compl Date: 24 Jan 85
(7) Principal Investigator: William J. Georgitis, MAJ, MC Tony L. Walden, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Medicine/Endocrine	(10) Assoc Investigators: Pritam S. Verma, Ph.D., CPT, MSC Gerald S. Kidd, LTC, MC / T.P. O'Barr, Ph Michael Bornemann, COL, MC/Ellen Swanson, Michael T. McDermott, MAJ, MC Albert McCullen, CPT, VC/Donald Corby, CO
(11) Key Words: androgens prostaglandins estrogens castration ACE	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: N/A  
 d. Total Number of Subjects Enrolled to Date: Animal Study  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

## (15) Study Objective:

To determine the effects of varying levels of androgens and estrogens on arachidonic acid metabolites, prostacyclin and thromboxane in laboratory animals. Addendum: To determine the effects of androgen and estrogen on serum and lung ACE activity.

## (16) Technical Approach:

Prostaglandin Studies: Men and postmenopausal women demonstrate an increased risk of atherogenic events compared to premenopausal women. This observation has spurred interest in the potential effects of gonadal steroids on atherogenic factors including certain arachidonic acid metabolites. Thromboxane A<sub>2</sub>, a potent vasoconstrictor and platelet aggregant, and prostacyclin, a potent vasodilator and platelet antiaggregant are two possibly important factors in atherogenesis.

The initial investigation failed to demonstrate an effect of sex steroids on the stable metabolites of thromboxane A<sub>2</sub> and prostacyclin, (TxB<sub>2</sub> and 6-keto-PGF<sub>1α</sub>), in male Sprague-Dawley rats divided into groups of sham castrated and castrated rats treated with vehicle alone, estradiol, and partial or full testosterone replacement.

To confirm and extend these observations, approximately 300 gm male Sprague-Dawley rats were divided into four groups as follows. sham castrates (Sham) given subcutaneous injections of sesame oil (SO) (n=6) or saline (SA) (n=7) for four weeks, castrates (Cx) given subcutaneous injections of sesame oil (n=9) or saline (n=9) for four weeks, and castrates given subcutaneous injections of 1 mg of testosterone propionate (Tsc) in sesame oil (n=9) for four weeks. After nebular

## (16) Technical Approach - continued:

anesthesia, serum for platelet counts was obtained. The TxB2 was measured by RIA after the addition of 50 U of thrombin to blood. Aortic rings were incubated in TRIS, NaCl buffer at pH 7.4 and 22 C for 15 mins. The 6-ketoPGF1a produced was measured by RIA.

ACE Addendums: Angiotensin-converting enzyme (ACE), a membrane bound exopeptidase that cleaves C-terminal dipeptides off peptide substrates, converts angiotensin I to angiotensin II and inactivates bradykinin. In humans activity varies with different disease states and differs between the sexes. This sex difference in activity is presumed to be of hormonal origin but has been incompletely studied.

Four groups of approximately 200 gm male castrated Sprague-Dawley rats were treated with either sesame oil (Cx), 60 mcg of testosterone propionate in sesame oil/100 gm body weight/day (Low T), 360 mcg of T/day (Full T), or estradiol benzoate 5 mcg/day (E2) for four weeks and compared with 12 sham castrated rats treated with vehicle alone (Sham). Serum ACE activity by radio-chemical assay, T, and E2 levels were compared.

To confirm and extend findings from the above experiment, we studied similar rats treated with pharmacologic doses of testosterone. Approximately 300 gm male, Sprague-Dawley rats were divided into four groups as follows: sham castrates (Sham) given subcutaneous injections of sesame oil (n=6) or saline (n=7) for four weeks, castrates (Cx) given subcutaneous injections of sesame oil (n=9) or saline (n=9) for four weeks, castrates given subcutaneous injections of 1 mg of testosterone propionate (Tsc) in sesame oil (n=9) for four weeks, or castrates implanted with Alzet minipumps delivering 1 mg of testosterone propionate (Tp) subcutaneously per day for three weeks. Serum was obtained from the inferior vena cava after nembutal anesthesia and assayed for ACE activity by a radiochemical method and testosterone by radioimmunoassay.

## (17) Progress:

Prostaglandin Studies: No significant differences in TxB2 or 6-ketoPGF1a was found in either study.

ACE Addendums: Serum ACE activity was lowered by castration of male rats. Estradiol treatment further depressed ACE and partial or full T replacement restored serum ACE activity to levels comparable to the sexually mature sham castrates.

Serum ACE activity is modulated by sex steroids as shown by the ability of androgen deficiency and estradiol treatment to lower and androgen replacement to restore ACE activity to noncastrate levels in male castrate rats.

Castration once again lowered serum ACE levels confirming the above result. In addition, treatment with 1 mg/day of testosterone both by daily subcutaneous injections or by continuous subcutaneous infusion not only restored but resulted in elevations in serum ACE activity.

Serum ACE activity can be affected by sex steroids as shown by the ability of androgen deficiency to lower and testosterone treatment to raise the serum activity of this enzyme.

SERVICE Endocrine

DEPARTMENT Medicine

- (1) Verma, P.S., Chadwick, E.W., and Georgitis, W.J.:  
Effects of Castration and Sex Steroid Treatment on Serum Angiotensin  
Converting Enzyme Activity. Presented: Endocrine Society Meeting,  
Baltimore, MD, 21 June 1985.
- (2) Georgitis, W.J., Walden, T.L., Kidd, G.S., and Verma, P.S.:  
Effects of Castration and Testosterone on Serum Angiotensin Converting  
Enzyme Activity. Presented: Concept Meeting, ACP, San Francisco,  
CA, 9 October 1985.

Publications:

Verma, P.S., Chadwick, E.W., and Georgitis, W.J.: Effects of Castration and  
Sex Steroid Treatment on Serum Angiotensin Converting Enzyme Activity. (Abst.)  
Endocrine Society 837:210, Baltimore, MD, 21 June 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/100 (3) Status: Ongoing  
(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C  
(FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric  
SWOG #7804 Adenocarcinoma, Phase III

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:  
(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/101 (3) Status: Ongoing  
 (4) Title: Combined Modality Treatment for Stages III and IV Hodgkin's Disease  
 - MOPP #6, Phase III  
 SWOG #7808

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 1 patient registered  
 No complications

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/102 (3) Status: Ongoing  
 (4) Title: Combined Modality Therapy for Breast Carcinoma, Phase III

SWOG # 7827

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 1 Patient registered  
 No complications

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/103 (3) Status: Terminated  
 (4) Title: Radiation Therapy in Combination with CCNU in Patients with  
 Incompletely Resected Gliomas of the Brain, Grade I and II,  
 SWOG #7983 Phase III.

(5) Start Date: (6) Est Compl Date:  
 (7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: Chemotherapy  
 Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.  
 Closed by SWOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/104 (3) Status: Ongoing  
 (4) Title: The Treatment of Chronic Stage CML with Pulse, Intermittent  
 Busalfan Therapy With or Without Oral Vitamin-A, Phase III  
 SWOG #7984

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	Torrence Wilson, COL, MC
Chemotherapy	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/105 (3) Status: ~~Terminated~~  
 (4) Title: Intergroup Testicular Study

SWOG # 7990

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.  
 Protocol closed March 1985 by SWOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/106 (3) Status: Terminated  
 (4) Title: Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

SWOG #8001

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

Closed by SWOG.  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/i07 (3) Status: Terminated  
(4) Title: Pre-Operative Reductive Chemotherapy for Stage III or IV Operable  
Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx or Larynx,  
SWOG #8006 Phase III.

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: Torrence Wilson, COL, MC  
Chemotherapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
Closed by SWOG.  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/108 (3) Status: Ongoing  
(4) Title: Combined Modality Therapy for Disseminated Soft Tissue Sarcoma,  
Phase III.

SWOG #8024

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	Torrence Wilson, COL, MC

Chemotherapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/109 (3) Status: Ongoing  
(4) Title: Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the  
Penis, Phase II.  
SWOG #8026

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/110 (3) Status: Ongoing  
 (4) Title: The Treatment of Resected, Poor Prognosis Malignant Melanoma: Stage I: Surgical Excision vs. Surgical Excision + Vitamin A, Phase III.

SWOG #8049

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/111 (3) Status: Ongoing  
(4) Title: (Intergroup Mesothelioma Study #1), Radiotherapy With and Without  
Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III.  
SWOG # 8094

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".)

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/112 (3) Status: Ongoing  
(4) Title: Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment  
of Solid Tumor Leptomeningeal Metastases, Phase II.

SWOG # 8102

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/113 (3) Status: Ongoing  
 (4) Title: Treatment of Advanced Seminoma (Stage cII(N<sub>4</sub>) + cIII) with Combined  
 Chemotherapy and Radiation Therapy, Phase II.

SWOG # 8104

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/114 (3) Status: Ongoing  
(4) Title: Management of Disseminated Melanoma, Master Protocol, Phase III.

SWOG # 8107

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/115 (3) Status: Ongoing

(4) Title: Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction with Vinblastine, Bleomycin & Cis-Platinum (VBP) Vs Vinblastine, Cis-Platinum & VP-16-213 (VPV); Surgical Removal of All Residual Tumor Following SWOG # 8110 Remission Induction; Comparison of Maintenance Therapy with Cyclophosphamide, Actinomycin-D, Adriamycin & Vinblastine vs Observation, Phase

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/116 (3) Status: terminated  
(4) Title: Combined Modality Treatment of Extensive Small Cell Lung Cancer,  
Phase III.  
SWOG # 8122

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: Torrence Wilson, COL, MC  
Chemotherapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

Closed by SWOG.  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/117 (3) Status: Ongoing  
(4) Title: Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction,  
Consolidation Chemotherapy: Maintenance with Chemotherapy vs Bone marrow Transplantation  
SWOG #8124/25/26 Following Total Body Irradiation, Phase II.

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/118 (3) Status: Ongoing  
 (4) Title: Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma,  
 Phase II.

SWOG # 8208

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/119 (3) Status: Terminated  
 (4) Title: Comparison of Combination Chemotherapy with VP-16 & Cis-Platinum vs BCNU, Thiotepe, Vincristine & Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase III  
 SWOG #8215

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.  
 Closed by SWOG

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/120 (3) Status: Ongoing  
(4) Title: Comparison of BCG Immunotherapy And Adriamycin for Superficial Bladder Cancer, Phase III.

SWOG # 8216/38

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:  
(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/121 (3) Status: Ongoing  
 (4) Title: Evaluation of Combined or Sequential Chemo-Endocrine Therapy in the Treatment of Advanced Adenocarcinoma of the Prostate, Phase III.  
 SWOG #8219

(5) Start Date: (6) Est Compl Date:  
 (7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/122 (3) Status: Ongoing  
 (4) Title: Treatment of Advanced Bladder Cancer with Preoperative Irradiation and Radical Cystectomy Versus Radical Cystectomy Alone, Phase III. SWOG #8221

(5) Start Date: (6) Est Compl Date:  
 (7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: Torrence Wilson, COL, MC  
 Chemotherapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/123 (3) Status: Ongoing  
(4) Title: Correlation Between Progesterone Receptor and Response to Tamoxifen  
Patients with Newly Diagnosed Metastatic Breast Disease, Phase II.  
SWOG # 8228

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/124 (3) Status: Ongoing	
(4) Title: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine + Prednisone for Maintenance or Consolidation. Evaluation of Half-Body Radiotherapy + Vincristine + Prednisone for Patients Who Fail to Achieve Remission with VMCP + Vincristine + Prednisone. SWOG # 8229/30 therapy + Vincristine-Prednisone for Patients Who Fail to Achieve Remission with VMCP + Vincristine + Prednisone.	
(5) Start Date:	(6) Est Compl Date: Remission Status with C
(7) Principal Investigator:	(8) Facility: FAMC therapy Alone, Phase II
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

- (14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_
- c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_
- d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_
- e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

patient registered.

complications.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/125 (3) Status: Ongoing  
(4) Title: Chemotherapy of Extragonadal Germinal Cell Neoplasms, Phase II.

SWOG # 8231

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_

d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/126 (3) Status: Ongoing  
(4) Title: Evaluation of Continuous Infusion Vinblastine in Gastric Carcinoma,  
Phase II.

SWOG # 8235

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/127 (3) Status: Terminated

(4) Title: Evaluation of Continuous Infusion Vinblastine in Pancreatic  
Adenocarcinoma, Phase II.

SWOG #8237

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: (12) Accumulative MEDCASE:\*

Chemotherapy

Torrence Wilson, COL, MC

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

Protocol closed by SWOG.

0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/128 (3) Status: Ongoing  
(4) Title: The Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II.

SWOG #8244

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/129 (3) Status: Ongoing  
 (4) Title: Intergroup Adult Adjuvant Soft Tissue Sarcoma Protocol #1, A Randomized Trial of Adjuvant Doxorubicin vs. Standard Therapy (A Delay of Chemotherapy U SWOG #8291 The Time of Possible Relapse), Phase III.

(5) Start Date: (6) Est Compl Date:  
 (7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:  
 (11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/130 (3) Status: Ongoing  
(4) Title: Treatment for Brain Metastases, Phase III. Intergroup Study.

SWOG # 8292

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/131 (3) Status: Ongoing  
(4) Title: Intergroup Phase III Protocol for the Management of Locally or Regionally  
Recurrent but Surgically Resectable Breast Cancer.

SWOG # 8293

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/132 (3) Status: Ongoing  
 (4) Title: Evaluation of Adjuvant Therapy and Biological Parameters in Node  
 Negative Operable Female Breast Cancer, Intergroup Study.  
 SWOG # 8294

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 10 patients registered.  
 0 complications.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/133 (3) Status: Ongoing  
(4) Title: Treatment of Limited Non-Small Cell Lung Cancer: Radiation Versus  
Radiation Plus Chemotherapy (FOMi/CAP), Phase III.

SWOG # 8300

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:\_\_\_\_\_ b. Review Results:\_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period:\_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date:\_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/134 (3) Status: Terminated  
 (4) Title: Combination Chemotherapy with Cis-Platinum, Vinblastine and MGBG in  
 Epidermoid Carcinoma of the Esophagus, Phase II.  
 SWOG # 8311

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 Protocol closed by SWOG.  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/135 (3) Status: Ongoing  
(4) Title: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Estrogen Receptor Positive SWOG #8312 Metastatic Breast Cancer, Phase III.

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:  
(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/136 (3) Status: Ongoing  
 (4) Title: Multiple Drug Adjuvant Chemotherapy for Patients with ER Negative Stage  
 Carcinoma of the Breast, Phase III.

SWOG # 8313

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/137 (3) Status: Ongoing  
(4) Title: Immediate Post-Operative Adjuvant Chemotherapy in Patients with  
Operable Breast Cancer, Phase II-Pilot.

SWOG #8364

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:  
(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/138 (3) Status: Ongoing  
(4) Title: Intergroup Adult Adjuvant Soft Tissue Sarcoma Protocol #2, A Randomized Trial of Adjuvant Doxorubicin vs. Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse), Phase III.  
SWOG #8391

(5) Start Date: (6) Est Compl Date:  
(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: (10) Assoc Investigators:

(11) Key Words: Torrence Wilson, COL, MC  
Chemotherapy

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/139 (3) Status: Ongoing  
(4) Title: National Intergroup Protocol for Intermediate Thickness Melanoma 1.0-4.0 mm  
Evaluation of Optimal Surgical Margins (2 vs 4 cm) Around the Primary Melanoma and  
SWOG #8393 Evaluation of Elective Regional Lymph Node Dissection.

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/140 (3) Status: Ongoing  
(4) Title: Combination Chemotherapy of Intermediate and High-Grade Non-Hodgkin's  
Lymphoma with m-BACOD, Phase II.  
SWOG #8410

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.  
Protocol closed by SWOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/141 (3) Status: Ongoing  
 (4) Title: Evaluation of DTIC in Metastatic Carcinoid, Phase II.

SWOG #8411

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	
Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/142 (3) Status: Ongoing  
(4) Title: Evaluation of Tamoxifen in Unresectable and Refractory Meningiomas,  
Phase II.

SWOG #8415

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/143 (3) Status: Ongoing  
(4) Title: Evaluation of Cisplatinum in Unresectable Diffuse Malignant Mesothelioma  
Phase II.

SWOG #8418

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:  Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/144 (3) Status: Ongoing  
(4) Title: Registration and Evaluation of Patients Aged 55 and Over with  
Unfavorable Histology NHL, Phase II-Pilot.  
SWOG #8461

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:  Chemotherapy	  Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/145 (3) Status: Ongoing  
(4) Title: Radiation Therapy + 5-Fluorouracil vs. Sandwich SMF Chemotherapy +  
Radiation Therapy as Adjuvant Surgical Treatment of Pancreatic Cancer,  
SWOG #8492, NCI Intergroup #0031. Phase III-Intergroup.

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:

(10) Assoc Investigators:

(11) Key Words:

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:

0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/146 (3) Status: Ongoing

(4) Title:

THE EFFECT OF GROWTH HORMONE ON ARACHIDONIC ACID METABOLITES

(5) Start Date: March 1985

(6) Est Compl Date: March 1987

(7) Principal Investigator:

Michael T. McDermott, MAJ, MC

Tony L. Walden, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine

(11) Key Words:

hyperthyroidism

thromboxane

prostacyclin

(10) Assoc Investigators:

Gerald S. Kidd, LTC, MC / Donald Corby, COL,

Michael Bornemann, COL, MC

William J. Georgitis, MAJ, MC

Albert McCullen, DVM, CPT, VC

T. Philip O'Barr, Ph.D., DCI

Ellen Swanson, MS, DCI

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 14 rats

d. Total Number of Subjects Enrolled to Date: 14 rats

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

None.

(15) Study Objective:

To determine the effect of excess growth hormone on platelet thromboxane production and aortic prostacyclin production in laboratory animals.

(16) Technical Approach:

Twelve rats are given daily injections of excess growth hormone; 12 control rats receive placebo injections. After one week the rats are sacrificed and platelets are studied for thromboxane production and aortic rings are studied for prostacyclin production.

(17) Progress:

Twenty-four rats have been studied. Assays and data analysis are pending.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/147 (3) Status: Ongoing  
 (4) Title: HLA and Gm genes in systemic lupus erythematosus antibody expression.

(5) Start Date: March 1985	(6) Est Compl Date: June 1986
(7) Principal Investigator: Christopher LeSueur Sterling West	(8) Facility: FAMC

(9) Dept/Svc: Medicine/Rheumatology	(10) Assoc Investigators: Peter A. Andersen, M.D. Moses Shanfield, PhD
(11) Key Words: Systemic lupus erythematosus HLA Gm genes	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: Zero  
 d. Total Number of Subjects Enrolled to Date: Zero  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

1) To see if patients with systemic lupus erythematosus have increased prevalence of any HLA and Gm genes as it relates to their autoantibody expression compared to a control group.

COMMENT: We have not been able to start this study due to the inability to secure money from the Department of Clinical Investion. If this delay continues, we will be unable to complete the proposed study in the time limits imposed.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/148 (3) Status: Ongoing  
(4) Title: Respiratory Failure Patient Rehabilitation Through Intermittent  
Respiratory Muscle Resting

(5) Start Date: 1985	(6) Est Compl Date: 1986
(7) Principal Investigator: David A. Thomas, MAJ, MC Jerry Pluss, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Pulmonary/MED	(10) Assoc Investigators:
(11) Key Words:	Michael E. Perry, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: Two  
d. Total Number of Subjects Enrolled to Date: Two  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) Define hemodynamic responses to chronic respiratory failure before and after intermittent respiratory muscle resting; b) define changes in exercise tolerance with an intermittent respiratory muscle resting program and c) define changes in pulmonary physiology and mechanical responses to a respiratory muscle resting program.

(16) Technical Approach: After patient education about the project and consent form signed the study is begun with multiple pulmonary function tests to assess present lung function. The patient is then admitted to the MICU for Swan Ganz placement to assess cardiac and pulmonary pressures and function. On the same day the patient is then begun on the negative pressure ventilator in the hospital. Approximately 5 days of hospitalization is required to then familiarize the patient and his family with the ventilator technique and its potential advantages. The patient is then sent home with the ventilator for a home trial with a qualified respiratory therapist monitoring home care. The patient is then returned to pulmonary clinic for reevaluation at 2 weeks, 6 weeks, 3 months and 6 months. At the six month period the patient is then readmitted to the hospital for extensive evaluation to include the initial type work up. The patient is then followed for an additional 6 months to complete the study with the end of the study evaluation to include pulmonary function testing and subjective questioning.

(18) Progress: Thus far in this particular study we have enrolled two patients. The first patient discontinued the bag ventilator due to vascular insufficiency in the lower extremities and difficulty with smoking. The only current patient in the study is about to be evaluated for her 6 month follow up in about 6 weeks. She notes subjective improvement in her ability to exercise but no change in pulmonary function testing has been noted as of yet.

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/149 (3) Status: Completed  
 (4) Title: THE EFFECT OF TRIIODOTHYRONINE (LT<sub>3</sub>) INDUCED HYPERTHYROIDISM  
 ON ARACHIDONIC ACID METABOLITES

(5) Start Date: March 1985 (6) Est Compl Date: March 1985  
 (7) Principal Investigator: Michael Bornemann, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine (10) Assoc Investigators:  
 (11) Key Words: triiodothyronine Gerald S. Kidd, LTC, MC  
 prostacyclin Michael T. McDermott, MAJ, MC  
 thromboxane William J. Georgitis, MAJ, MC  
 Tony L. Walden, CPT, MC / Ellen Swanson,  
 T. P. O'Barr, Ph.D. / Donald Corby, C

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period: N/A  
 d. Total Number of Subjects Enrolled to Date: Animal Study  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:  
 The objective of this study is to determine the effects of triiodothyronine-induced hyperthyroidism on arachidonic acid metabolites (prostacyclin and thromboxane) in laboratory animals.

(16) Technical Approach:  
 The chronic effects of triiodothyronine (LT<sub>3</sub>) on arachidonic acid metabolites in the mature Sprague-Dawley rat was examined by subcutaneously injecting LT<sub>3</sub> for four weeks and then sacrificing the animals. The acute effects were studied by injecting LT<sub>3</sub> 2 hours before sacrificing the rats. The control rats were used for both phases of the experiment.

(17) Progress:  
 The study was initiated and completed during the 1985 fiscal year. Preliminary results were analyzed and submitted as an abstract to the Endocrine Section, Current Concepts of Internal Medicine Course scheduled for October 1985 in San Francisco. The abstract was not accepted. No other presentations or publications have arisen from this protocol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/150 (3) Status: Ongoing	
(4) Title: Reactive hyperemia as a function of control and duration of disease in the Type I diabetic.	
(5) Start Date: 1 Apr 85	(6) Est Compl Date: 31 Mar 86
(7) Principal Investigator: Robert H. Slover, M.D., Major(P), MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators:
(11) Key Words: Reactive hyperemia, diabetes control	Mark S. Hayes, M.D., CPT, MC Ronald J. Portman, M.D., MAJ, MC Michael Shull, M.D., CPT, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: 14	
d. Total Number of Subjects Enrolled to Date: 14	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.	
(15) Study Objective: Transcutaneous oxygen monitoring of hyperemic response could serve as a rapid screen of glucose control in a population and of changing patterns of control longitudinally in an individual patient. In order to answer questions about its efficacy, we plan to study 10 patients with duration of disease greater than five years, 10 with duration 5-10 years, and 10 with duration greater than ten years, as compared to a population of 60 controls. We shall determine post ischemic hyperemia in each child. In diabetic subjects we plan to obtain serum glycohemoglobin, creatinine, 24-hour urine for creatinine clearance and glucose and to determine mean blood glucose. We will analyze data obtained in the following areas: TC02, (transcutaneous PO2, ischemia, TC02 maximal response to post ischemic state and time to return to baseline (duration of response).	
(16) Technical Approach: Subjects are studied with a transcutaneous oxygen monitor with the electrode (37°) placed on the left forearm allowing ten minutes for equilibration. Pre-ischemic TC02 is recorded. Blood pressure cuff is inflated to 40-50 mm mercury above noted systolic pressure and left in place for four minutes. Following deflation of the cuff TC02 is recorded for ten minutes or until it returns to baseline, noting maximal TC02 and time to recovery. In diabetic patients hemoglobin A1C, mean blood glucose, GFR, and 24-hour urinary glucose are obtained.	
(17) Progress: Study was begun in FY 85. Subsequent to protocol approval, we have trained two residents in the use of the transcutaneous oxygen monitor. We	

have procured and calibrated the equipment and have run approximately 25 preliminary patients to familiarize ourselves with its use. We have developed the assay for urinary albumin. We have compiled a list of diabetic patients and have begun the study group and control group on the protocol. To date, we have studied approximately twenty patients and controls. We anticipate completion of the data collection by 1 Jan 86.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/151 (3) Status: Ongoing  
(4) Title:

ADRENAL FUNCTION IN MALIGNANCY

(5) Start Date: 22 June 1980	(6) Est Compl Date: 30 June 1986
(7) Principal Investigator: Michael T. McDermott, MAJ, MC Tony L. Walden, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: <u>Medicine/Endocrine</u>	(10) Assoc Investigators: Michael Witte, MAJ, MC Elder Granger, CPT, MC Gerald S. Kidd, LTC, MC
(11) Key Words:  bronchogenic carcinoma impaired adrenal reserve	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: 45 patients with bronchogenic C.  
d. Total Number of Subjects Enrolled to Date: 55 10 control patie  
e. Note any adverse drug reactions reported to the FDA or sponsor for stud-  
ies conducted under an FDA-awarded IND. (May be continued on a separate  
sheet, and designated as "(14)e".

None.

(15) Study Objective:

Identify, premortem, those patients with known bronchogenic carcinoma and impaired adrenal reserve secondary to adrenal metastases.

(16) Technical Approach: A short ACTH stimulation test will be completed on patients with biopsy proven bronchogenic carcinoma. Patients being treated with steroid preparations will be excluded.

(17) Progress: Two of 45 patients with bronchogenic carcinoma had evidence of decreased adrenal reserve with serum cortisol levels less than 20 ug% (peak cortisol = 6.1 ug% and 11.3 ug%, respectively) after 0.25 mg Cosyntropin was injected intravenously. Ten patients without bronchogenic carcinoma (control patients), age, sex and medical systemic illness matched, had normal serum cortisol levels at 30 and 60 minutes after 0.25 mg Cosyntropin was injected intravenously. Other control patients have been studied. Results are pending at this time.

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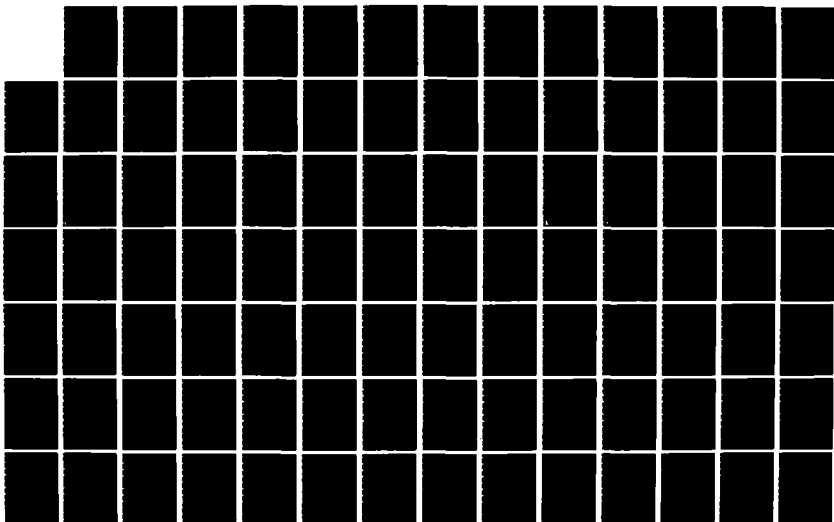
CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT  
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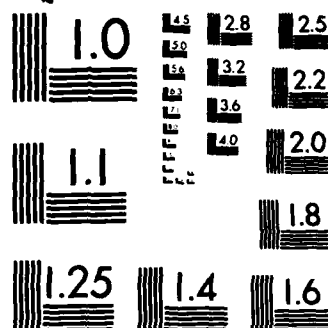
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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/152 (3) Status: ONGOING

(4) Title:

**ASSESSMENT OF THE INCIDENCE OF BRONCHIAL HYPERREACTIVITY TO METHACHOLINE IN PATIENTS WITH SARCOIDOSIS**

(5) Start Date: DEC, 1984

(6) Est Compl Date: JUNE 1985

(7) Principal Investigator:

Thomas, David A. MAJ MC MD  
Olsen, John CPT MC MD  
Nelson, Harold S. COL MC MD

(8) Facility: FAMC  
PULMONARY CLINIC  
ALLERGY CLINIC

(9) Dept/Svc: PULM/ALLERGY

(11) Key Words:

(10) Assoc Investigators:

Witte, Michael C. MC MD MAJ

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 17 patients

d. Total Number of Subjects Enrolled to Date: 17 patients

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

NONE

(15) Study Objective:

To determine the frequency with which nonspecific bronchial hyperreactivity to methacholine occurs in consecutive patients with sarcoidosis.

(16) Technical Approach:

All patients presenting to FAMC as inpatients or outpatients with the diagnosis of sarcoidosis by biopsy confirmation without previous therapy with systemic corticosteroids are considered eligible for the study. If the patient consents to the study an initial evaluation to consist of routine pulmonary function tests, chest x-ray and blood tests are done. The patient then has a methacholine challenge test performed to assess possible reactive airway disease.

(17) Progress: Thus for seventeen (17) patients have been enrolled in the study and have undergone initial evaluation and the methacholine challenge tests without complication. We have found 3/17 patients to have bronchial reactivity consistent with an asthma like state. There have been 2 additional patients with reactive airway like symptoms but with methacholine challenge tests that are just below the criteria set for bronchial reactivity.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/153 (3) Status: Ongoing	
(4) Title: Simultaneous Cis-Platinum + Radiation Therapy Compared with Standard Radiation Therapy in the Treatment of Unresectable Squamous or Undifferentiated Carcinoma of the Head & Neck, Phase III.	
SWOG #8493	
(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC
Arlene J. Zaloznik, MAJ, MC	
(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	Torrence Wilson, COL, MC
Chemotherapy	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: _____	
d. Total Number of Subjects Enrolled to Date: _____	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	
(15) Study Objective:	
The objective is to participate in the SWOG group in the study of adult oncological malignancies.	
(16) Technical Approach: See Protocol.	
(17) Progress:	
0 patients registered.	

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/154 (3) Status: Ongoing  
(4) Title:

**THE EFFECT OF HYPERTHYROIDISM ON ARACHIDONIC  
ACID METABOLITES**

(5) Start Date: July 1984 (6) Est Compl Date: December 1985

(7) Principal Investigator: (8) Facility: FAMC

Michael T. McDermott, MAJ, MC

(9) Dept/Svc: Medicine/Endocrine

(11) Key Words:

hyperthyroid

rats

arachidonic acid metabolites

(10) Assoc Investigators:

Robert J. Sjoberg, CPT, MC

Gerald S. Kidd, LTC,

Michael Bornemann, COL, MC

Tony L. Walden, CPT, MC

T. Phillip O'Barr, Ph.D., DAC

Donald Corby, COL, MC

Ellen Swanson, MS, D

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 60

d. Total Number of Subjects Enrolled to Date: 60

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective: The objective of this study is to determine the effects of hyperthyroidism on arachidonic acid metabolites, prostacyclin, and thromboxane in laboratory animals.

(16) Technical Approach: Forty -eight male Sprague-Dawley rats were divided into 24 litter mate pairs. One member of each pair received daily subcutaneous injections of thromboxane in doses (10 ug/100 gm/day) for 5 times weekly, while the control rat received subcutaneous injections of saline. Twelve rat pairs were treated for 4 weeks; the other 12 pairs were treated for 12 weeks. Following the treatment period, the sacrificed animals were sacrificed and serum glucose, insulin, cholesterol, and serum T4 levels were measured. Platelet thromboxane B2 generation, aortic 6-ketoPGF1 $\alpha$  generation and renal medullary PGE2 generation was measured.

(17) Progress: The data from the rats treated for 4 weeks demonstrated that thyroid hormone given exogenously in supernormal amounts caused a significant reduction in platelet thromboxane A2 production, but did not substantially effect aortic PGI2 production. Upon completion of the 12 week treatment period thyroid hormone levels measured in each of the 24 rats including the 12 control rats (scheduled to be given injections of normal saline) indicated that all rats in the 12 week treatment group

## (17) Progress - continued:

had inadvertently been given an injection of Synthroid at some time during the 12 week treatment period. Therefore, an additional 12 rats were purchased and given normal saline for 12 weeks to be used as a control group for the previously studied 12 week rats treated with subcutaneous thyroxine 10 ug/100 gm/day. Results of the 12 week group is pending at this time.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/155 (3) Status: Ongoing  
(4) Title:

ATELECTASIS WITH HIGH FREQUENCY VENTILATION

(5) Start Date: June, 1985	(6) Est Compl Date: June, 1986
(7) Principal Investigator: David A. Thomas, Maj MD MC Michael E. Perry, Col, MD MC	(8) Facility: FAMC
(9) Dept/Svc: Pulmonary Service	(10) Assoc Investigators: Eric Allely, Lt. MC Res.
(11) Key Words:  HFJV AND ATELECTASIS	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: Nine  
d. Total Number of Subjects Enrolled to Date: Nine  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The purpose of this study is to evaluate changes in tidal volume that may occur as a result of atelectasis with high frequency jet ventilation.

(16) Technical Approach:

Anesthetized mongrel dogs are placed into a body plethysmograph unit and ventilated with a High Frequency Jet Ventilator. Vital statistics of the dog are monitored such as blood pressure, heart rate, and tidal volume. The dogs are ventilated to a steady state as determined by arterial blood gases and tidal volume measurements with the addition of a sigh of 14 tidal breaths every 5 minutes. When a stable state is reached then pressure volume measurements are taken to determine the baseline static compliance of the dog's lungs. The dog is then ventilated to steady state again with the sigh technique. The sigh is discontinued when steady state is reached and ventilation continued. Tidal volume measurements and arterial blood gases are obtained to assess for possible changes in lung compliance and to detect atelectasis. Once changes are seen that suggest atelectasis or the dog has been ventilated for two hours pressure volume measurements are again taken to detect changes in lung static compliance. The study is then completed.

## (17) Progress:

Thus far in this study we have studied nine mongrel dogs with the techniques previously described. One set of data (dog no. 4) had to be discarded due to power failure during a crucial part of the study. Therefore we have collected data from eight dogs and evaluate that data.

With every study performed thus far there has been significant changes in the tidal volumes, blood gases, and static compliances after the sigh is discontinued indicating appearance of atelectasis without the use of the sigh to maintain adequate tidal volume. These changes are all significant with the means showing definite P values less than 0.05 using paired observations.

This data is very important in that atelectasis has not been shown to be problem with HFJV up to this point in the literature.

The study is still ongoing in that control dogs studies need to be performed in which the dogs are ventilated with the sigh technique for the entire study time to show that the sigh does prevent atelectasis with long term ventilation.

Publications: None

Presentations:

Thomas, D.A., Perry, M.E.: Atelectasis with High Frequency Jet Ventilation. Presented: Present Concepts in Internal Medicine: Pulmonary Subsection, Letterman Army Medical Center, San Francisco, California, October 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/156 (3) Status: ongoing  
 (4) Title: Clinical Effectiveness and development of subsensitivity with chronic administration of atropine methonitrate.

(5) Start Date: not started	(6) Est Compl Date: 1986
(7) Principal Investigator: HS Nelson, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: MED/Allergy	(10) Assoc Investigators:
(11) Key Words: atropine methonitrate  subsensitivity	R. Vaughan, MAJ, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period: 0  
 d. Total Number of Subjects Enrolled to Date: 0  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". none

- (15) Study Objective. To determine the response to atropine methonitrate administered by jet nebulization compared to the response to placebo.
- (16) Administer in a double-blind crossover manner for 2-wks each placebo and the atropine methonitrate 4 times daily. At the end of each 2-wk trial subjects will report to the Allergy Clinic where the pulmonary response to inhalation of the drug employed for the previous 2 wks will be measured. A comparison of the response after 2 wks of 4times daily administration of atropine methonitrate to the response prior to the administration of atropine methylnitrate will determine the development of subsensitivity. Home monitoring of peak flow rates, asthma symptom scores and requirement for supplementary inhaled medication during the 2 wk period on atropine methonitrate compared to the 2wk period on placebo will determine the efficacy of regular administration of inhaled atropine methonitrate.

17) Progress: Approval has only been obtained within the last 2 wks. for this protocol.

Publications and presentations None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/157 (3) Status: Ongoing  
(4) Title: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck

SWOG # 8590

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol.

(17) Progress:  
0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/158 (3) Status: Ongoing  
 (4) Title: NCI Intergroup #0035, An Evaluation of Levamisole Alone or Levamisole Plus 5-Fluorouracil as Surgical Adjuvant Treatment for Resectable Adenocarcinoma of the Colon, Phase III-Intergroup.  
 SWOG #8591

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: Arlene J. Zaloznik, MAJ, MC	(8) Facility: FAMC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words: Chemotherapy	Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:  
 The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
 0 patients registered.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/159 (3) Status: Ongoing  
(4) Title: Cyclophosphamide, Methotrexate and 5-Fluoracil in the Treatment of Stage D2 Adenocarcinoma of the Prostate, Phase II.

SWOG # 8421

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator:	(8) Facility: FAMC

Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc:	(10) Assoc Investigators:
(11) Key Words:	

Chemotherapy

Torrence Wilson, COL, MC

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress:  
0 patients registered.

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/160 (3) Status: Ongoing  
 (4) Title: THE EFFECT OF HYPOTHYROIDISM ON GROWTH HORMONE RELEASING FACTOR AND SOMATOSTATIN

(5) Start Date: June 1985 (6) Est Compl Date: June 1987  
 (7) Principal Investigator: Michael T. McDermott, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Medicine/Endocrine (10) Assoc Investigators:  
 (11) Key Words: Gerald S. Kidd, LTC, MC  
 hypothyroidism Ellen Swanson, MS, DAC, DCI  
 growth hormone releasing factor Bill Leidy, MD, UCHSC  
 (GHRH)  
 somatostatin

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period: 45 rats  
 d. Total Number of Subjects Enrolled to Date: 45 rats  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:

To determine the effects of primary hypothyroidism on hypothalamic production of GHRH and somatostatin in laboratory animals.

(16) Technical Approach:

Fifteen rats are made hypothyroid by adding methimazole to their drinking water; 15 rats have methimazole in their water and get daily Synthroid injections to remain euthyroid; 15 rats have normal water and daily saline injections. After 4 weeks all rats are sacrificed by decapitation. Serum is analyzed for thyroid hormones, TSH and GH. The hypothalami are weighed and analyzed for GHRH and somatostatin.

(17) Progress: Forty-five rats have been studied. Hormone assays and data analysis are pending.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/161 (3) Status:ongoing

(4) Title:  
TRANSTRONCHIAL NEEDLE ASPIRATION AND ITS ROLE IN LUNG CANCER STAGING

(5) Start Date:1 MAY 85 (6) Est Compl Date:1 JUL 86

(7) Principal Investigator:  
DAVID A. THOMAS, M.D., MAJ, MC  
JOHN D. OLSEN, M.D., CPT, MC

(8) Facility: FAMC

(9) Dept/Svc:DOM / PULM DIS SVC

(11) Key Words:  
TRANSTRONCHIAL NEEDLE ASPIRATION  
LUNG CANCER STAGING

(10) Assoc Investigators:

MICHAEL E. PERRY, M.D. COL, MC  
THOMAS PEZZELLA, M.D., LTC, MC  
KENNETH HOPPER, M.D. MAJ, MC  
VISHNU REDDY, M.D., LTC, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:18

d. Total Number of Subjects Enrolled to Date: 18

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". N/A

(15) Study Objective:

- (1). Determine the accuracy, sensitivity, and specificity of TBNA in lung cancer staging
- (2). Determine the accuracy, sensitivity, and specificity of TBNA in comparison to Chest CT scan, Mediastinoscopy and Mediastinotomy
- (3). Further define the safety of TBNA and its diagnostic utility

17) PROGRESS:

To date 18 patients have been enrolled. One patient had non-malignant diagnosis, the remainder had lung cancer. 6 of 17 had (+) TBNA 1 was a false positive. All (-) TBNA's have been true negatives. Sensitivity = 100%; Specificity =90%; accuracy = 92%. Only one complication: mediastinal hemorrhage from TBNA, resolved with conservative management. No serious complications; no deaths.

Presented: Olsen, J.D., Thomas, D.A., Perry, M.E.: Transbronchial Needle Aspiration in Lung Cancer Staging. Presented. Annual Army ACP Meeting, San Francisco, CA, October 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/162 (3) Status: Ongoing

(4) Title: Use of Topical Solution for Treatment Related Stomatitis: A Double-blind, Cross over Study

(5) Start Date: July 1984

(6) Est Compl Date: June 1987

(7) Principal Investigator:

(8) Facility: FAMC

Don B. Blakeslee, LTC, MC  
Arlene J. Zaloznik, MAJ, MC

(9) Dept/Svc: DOS -Otolaryngology

(10) Assoc Investigators:

(11) Key Words:

Topical Treatment Stomatitis

Arlene J. Zaloznik, MAJ, MC  
Dept. Medicine Hematology/Oncology  
R. Eugene Leinert, M.D.  
Dept Radiology Radiation Oncology

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 8

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

To determine the relative efficiency of three commonly used topical solutions for relief of pain secondary to stomatitis caused by radiation or oncologic therapy.

To determine the long term efficiency of a selected solution in palliation of stomatitis.

(16) The technical approach is a double-blind, cross over study.

(17) The progress during fiscal year 1985 is slow. We anticipate a minimum of 25 patients to complete the study during the next fiscal year.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/163 (3) Status: Completed

(4) Title:

The Effect of Theophylline and Nifedipine on Hormone Secretion

(5) Start Date: Sep 84

(6) Est Compl Date: Dec 84

(7) Principal Investigator:  
Michael T. McDermott, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc:

(11) Key Words:  
theophylline  
nifedipine  
hormone secretion

(10) Assoc Investigators:

Tony L. Walden, CPT, MC  
Gerald S. Kidd, LTC, MC  
Fred D. Hofeldt, COL, MC  
Michael Bornemann, COL, MC  
Robert J. Sjoberg, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 6

d. Total Number of Subjects Enrolled to Date: 6

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:

To determine the effect of calcium channel blockade and enhanced intracellular cAMP on adrenal and pituitary hormone secretion.

(16) Technical Approach:

ACTH, TRH and GnRH are performed in volunteer subjects during three separate periods: control, while on oral nifedipine, and during a theophylline infusion.

(17) Progress:

Study complete. Calcium channel blockade does not affect secretion of any of the hormones tested. Theophylline enhances cortisol, tSH and T<sub>3</sub> secretion. Three papers have been written and submitted for publication.

PUBLICATIONS: Submitted for publication

PRESENTATIONS: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/164 (3) Status: Terminated

(4) Title:  
PULMONARY VASCULAR VASOSPASM IN RAYNAUD'S DISEASE AND PROGRESSIVE SYSTEMIC  
SCLEROSIS: PREVALENCE AND RESPONSE TO NIFEDIPINE.

(5) Start Date: 1985 (6) Est Compl Date: Terminated

(7) Principal Investigator:  
Matthew J Mc Mahon DO MAJ MC (8) Facility: FAMC

(9) Dept/Svc: Dept Med/Cardio Svc (10) Assoc Investigators:

(11) Key Words:  
Pulmonary vasospasm  
Raynaud's  
Scleroderma

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: None

d. Total Number of Subjects Enrolled to Date: None

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective:  
NA

(16) Technical approach:  
NA

(17) Major McMahon was transferred prior to enrolling any patients -- the study has been terminated.

Publications and presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:85/165 (3) Status: on-going  
 (4) Title: An evaluation of cross allergenicity among pollen extracts of members of the Chenopodiaceae and Amaranthaceae.

(5) Start Date: 1985	(6) Est Compl Date: 1986
(7) Principal Investigator: R.W. Weber, MD., COL MC	(8) Facility: FAMC Allergy Research lab Bldg 600 Immunology lab Bldg 601 Animal Facility
(9) Dept/Svc: Medicine/Allergy	(10) Assoc Investigators:
(11) Key Words: pollen cross-allergenicity Chenopod-Amaranth	H.S. Nelson, M.D., COL MC R. Ledoux D. Goodman, M.D., CDR MC W. Rickman, Ph.D., CPT MSC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: N/A  
 d. Total Number of Subjects Enrolled to Date: N/A  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To evaluate patterns of cross allergenicity among pollens of the weed families, Chenopodiaceae and Amaranthaceae.

(16) Technical Approach: Anti-sera will be raised in rabbits and subjected to crossed immunoelectrophoresis and cross radioimmuno-electrophoresis to identify antigenic proteins and allergenic proteins. Western blot technique will be used to separate constituents. Cross allergenicity will be assessed by ELISA inhibition with human allergenic sera.

(17) Progress: Rabbits have been procured. Dried pollen has been obtained and has been defatted and dialysed pending lyophilization to produce potent and stable extracts.

Presentations and Publications: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/166 (3) Status: Ongoing  
 (4) Title: Colon Inflammation in Reiter's Syndrome: Response to Sulfasalazine. Results of a controlled study.

(5) Start Date: July 1985	(6) Est Compl Date: July 1989
(7) Principal Investigator: David Nordstrom, M.D. Sterling West, M.D. Peter Andersen, M.D. Frank Moses, M.D.	(8) Facility: FAMC

(9) Dept/Svc: Medicine/Rheumatology	(10) Assoc Investigators:
(11) Key Words: Reiter's syndrome Sulfasalazine	Brian Andersen, Robert Hawkins Ralph Houk Gary Klipple Jim Yovanoff Allen Wehrle

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: two  
 d. Total Number of Subjects Enrolled to Date: two  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".  
 None

(15) Study Objective:  
 1) To see if patients with idiopathic Reiter's syndrome have colon inflammation  
 2) To see (in double blinded fashion) if this responds to Sulfasalazine

(16) Progress: Study is new, no progress as of this date.

**SURGERY**

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 73/219 (3) Status: Terminated  
(4) Title: Urinary Tract Trauma

(5) Start Date: 1983	(6) Est Compl Date: 1986
(7) Principal Investigator: Michael J. Raife, M.D.	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators:
(11) Key Words: trauma, renal transplantation	Wilson, Torrence, COL, MC Horne, Daniel, M.D.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Evaluation of the role of ex vivo surgical repair of the traumatized renal unit, and the subsequent autotransplantation of the repaired units, for various types of renal injury.

(16) Technical Approach: Kidneys will be subjected to blunt and sharp trauma, including vascular trauma, and repair will be undertaken as bench surgery.

(17) Progress: Due to restrictions of dogs in research, the protocol is terminated and will be resubmitted using a different animal model.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/200 (3) Status: Terminated  
 (4) Title: Anastomosis of the Dog Vas Deferens Using Microsurgical Techniques

(5) Start Date: April 1978	(6) Est Compl Date: Terminated
(7) Principal Investigator: COL T. M. Wilson, MC Chief, Urology Service	(8) Facility: FAMC

(9) Dept/Svc: Surgery/Urology	(10) Assoc Investigators:
(11) Key Words: Microsurgery Vasovasostomy	LTC M.J. Raife LTC D.W. Horne CPT W.W. Vaught CPT D.L. Jones MAJ I.C. Castillo

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: N/A  
 d. Total Number of Subjects Enrolled to Date: N/A  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: To master microsurgical anastomosis of the vas deferens

(16) Standard two-layered microsurgical vasovasostomy performed on mongrel dogs using 9-0 nylon.

(17) Progress: Due to limitations on canine animal models, this protocol is terminated and will be replaced with training protocols using the rat or rabbit model for microsurgical training and using the pig for vasovasostomy microsurgical training.

*Michael J. Raife*

Michael J. Raife, M. D.  
 LTC MC  
 Asst C, Urology Svc

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/201 (3) Status: Ongoing  
(4) Title:

Clinical Study for Intraocular Lens

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: FLOYD M. CORNELL, LTC, MC	(8) Facility: FAMC FITSIMONS ARMY MEDICAL CENTER AURORA, COLORADO
(9) Dept/Svc: Ophthalmology	(10) Assoc Investigators:
(11) Key Words: intraocular lens	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 1050  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (1) To determine postoperative visual acuity of patients receiving an intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens; (2) To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant subject and for control subjects; (3) To compare the occurrence of adverse reaction and ocular complications in the implant group and in the control group, in order to delineate any significant difference (4) To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications. and (5) To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16) Technical Approach: After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery. Post operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: We have now implanted 1050 intraocular lenses. As a result of the past five years experience, we have evolved better guidelines for postoperative care. Our study includes tabulation of operative complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error. The results of every ophthalmologist implanting intraocular lenses in the United States is additionally compiled by computer in Washington, D.C. by the FDA. Our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result of this study many intraocular lenses have been taken off the protocol due to their proven safety. These devices that have been taken off the protocol study need only be registered when implanted at this time. Others have been discontinued from manufacture as a result of the development of superior lens devices.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/201 (3) Status: OnGOING

(4) Title: Clinical Study for Intra-Ocular Lenses

(5) Start Date: 1984	(6) Est Compl Date: UNKNOWN
(7) Principal Investigator: TOMAS CORONADO, M.D.	(8) Facility: FAMC GENERAL LEONARD WOOD ARMY COMMUNITY HOSPITAL FORT LEONARD WOOD, MISSOURI 75473-5700
(9) Dept/Svc: Ophthalmology	(10) Assoc Investigators: None
(11) Key Words: intraocular lenses	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: Aug 1984 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 54  
d. Total Number of Subjects Enrolled to Date: 54  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". One intraocular lens was removed due to mal-position

(15) Study Objective: (1) To determine postoperative visual acuity of patients receiving an intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens; (2) To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant subjects and for control subjects; (3) To compare the occurrence of adverse reaction and ocular complications in the implant group and in the control group, in order to delineate any significant difference; (4) To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications; and (5) To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16) Technical Approach: After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery. Postoperative examination include: keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: We have now implanted 57 intraocular lenses. As a result of this experience, we have evolved better guidelines for postoperative care. Our study includes tabulation of operative complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error. The results of every ophthalmologist implanting lenses in the United States is additionally compiled by computer in Washington, DC by the FDA. Our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result many intraocular lenses have been taken off the protocol due to their proven safety. These devices that have been taken off the protocol study need only be registered when implanted at this time. Others have been discontinued from manufacture as a result of the development of superior devices.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78/201 (3) Status: Ongoing  
(4) Title: Clinical Study for Intraocular Lens

(5) Start Date: July 1980	(6) Est Compl Date: Unknown
(7) Principal Investigator: RONALD R. HOLWEGER, M.D.	(8) Facility: FAMC IRWIN ARMY COMMUNITY HOSPITAL FT. RILEY, KANSAS
(9) Dept/Svc: Ophthalmology	(10) Assoc Investigators: None
(11) Key Words: intraocular lens	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: May 1985b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 147  
d. Total Number of Subjects Enrolled to Date: 147  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (1) To determine postoperative visual acuity of patients receiving an intraocular lens, and to compare those results with those of a control group of patients who undergo cataract surgery but do not receive an intraocular lens; (2) To describe the occurrence and time course of postoperative ocular complications and adverse reactions both for intraocular lens implant subject and for control subjects; (3) To compare the occurrence of adverse reaction and ocular complications in the implant group and in the control group, in order to delineate any significant difference; (4) To describe the occurrence of postoperative lens complications for the implant group, and their relationship to ocular complications. and (5) To identify subgroups within the implant study population that are at "high risk" of particular complications as compared to the control group.

(16) Technical Approach: After didactic courses, observations, laboratory practice and assistance with an experienced implant surgeon, a surgeon who can perform an accomplished cataract extraction, is then allowed to perform intraocular lens surgery. Post operative examinations include: pachymetry, keratometry and specular microscopy. Contraindications to surgery include: patients with good visual potential in only one eye, proliferative diabetic retinopathy, rubeosis irides, high axial myopia, and inadequately controlled glaucoma, Fuch's endothelial dystrophy.

(17) Progress: We have now implanted 147 intraocular lenses. As a result of the past five years experience, we have evolved better guidelines for postoperative care. Our study includes tabulation of operative complications, postoperative complications, visual results, endothelial cell loss, corneal thickness changes, changes in corneal astigmatism, and residual refractive error. The results of every ophthalmologist implanting intraocular lenses in the United States is additionally compiled by computer in Washington, D.C. by the FDA. Our results are a small part of this overall study. Final data from this massive study is to be completed in the future. As a result of this study many intraocular lenses have been taken off the protocol due to their proven safety. These devices that have been taken off the protocol study need only be registered when implanted at this time. Others have been discontinued from manufacture as a result of the development of superior lens devices.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/201 (3) Status: Completed	
(4) Title: Prospective Double Blind Randomized Study of the Effects of Supplemental Dietary Calcium and Vitamin D on the Healing of Distal Radius Fractures in Adults	
(5) Start Date: January 1982	(6) Est Compl Date: 1986
(7) Principal Investigator:  Timothy S. Loth, M.D. Captain, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Orthopedic	(10) Assoc Investigators:
(11) Key Words: Dietary Calcium Dietary Vitamin D Fractures	Steve Flood, M.D., CPT, MC Peter Blue, M.D., LTC, MC Nasser Ghaed, M.D., COL, MC
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: 4/84 b. Review Results: Ongoing	
c. Number of Subjects Enrolled During Reporting Period: 6	
d. Total Number of Subjects Enrolled to Date: 20	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

(15) Study Objective: To determine whether dietary calcium can increase the rate and quality of fracture healing.

(16) Technical Approach: Volunteers will be assigned randomly to Group A (which will receive calcium and vitamin D) or Group B (which will receive placebo). Bone densities will be performed on both wrists 3,6,12, and 4 weeks after fracture. An additional bone density will be performed within 1 week of fracture on the uninjured extremity to act as a control. After 50 cases have been collected the code will be broken for this study.

(17) Progress: We have enrolled 20 patients in the study thus far. The study is completed and data is being evaluated.

Publications and Presentations: None.

FAMC A.P.R. (RCS MFD 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

- |   |  |
|---|--|
| (1) Date: 30 Sep 85 (2) Protocol WU#: 82/203-N (3) Status: Ongoing  |  |
| (4) Title:<br>Effectiveness of EMG Biofeedback in Maintaining Fluency Obtained in an Intensive Stuttering Treatment Program   |  |
| (5) Start Date: 1982  | (6) Est Compl Date: 30 months after start                |
| (7) Principal Investigator:<br><br>Jon M. Hasbrouck, Ph.d.  | (8) Facility: FAMC                                       |
| (9) Dept/Svc: Surgery/Speech Path   | (10) Assoc Investigators:<br><br>Fran Lowry-Romero, M.S. |
| (11) Key Words:<br>Stuttering<br>Biofeedback  |  |
| (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*   |  |
| *Refer to Unit Summary Sheet of this report.  |  |
| (14) a. Date, Latest HUC Review: b. Review Results:   |  |
| c. Number of Subjects Enrolled During Reporting Period: 8   |  |
| d. Total Number of Subjects Enrolled to Date: 36  |  |
| e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").  |  |
| (15) Study Objective: Compare effects of extensive EMG biofeedback training and practice to EMG monitoring with no biofeedback and to no EMG monitoring and no biofeedback, to determine how EMG biofeedback related to the acquisition and maintenance of fluency in an intensive adult stuttering treatment program.  |  |
| (16) Technical Approach: SS in 3 groups will be pretested, receive 3 concurrent treatment procedures (airflow, relaxation, biofeedback) followed by a 4th treatment (discriminative stimulus control) and be post-tested. Grp 1 will receive extensive EMG biofeedback monitoring, training, and practice. Grp 2 will receive the same treatment as Grp 1, but will receive no auditory and visual feedback of performance. Grp 3 will receive no EMG biofeedback training or monitoring, but will receive the same amount of time in activities similar to Grps 1 and 2. |  |
| (17) Progress: During this fiscal year, 8 subjects in Grp 3 have completed the specified treatment program and have been followed on a regular basis since release from treatment. When followup of this final group of SS is complete, the study will be complete.   |  |

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/200 (3) Status: Completed

(4) Title: Evaluation of a Nonabsorbable Anterior Cruciate Ligament Prosthesis

(5) Start Date: 1983

(6) Est Compl Date: 1985

(7) Principal Investigator:

(8) Facility: FAMC

Walton W. Curl, LTC, MC

(9) Dept/Svc: Sur/Orthopedic

(10) Assoc Investigators:

(11) Key Words:  
anterior cruciate ligament and  
prosthesis

Ricky Wilkerson, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 12

d. Total Number of Subjects Enrolled to Date: 30

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine efficacy of repairing a ruptured anterior cruciate ligament and stinting this repair with an artificial ligament. To determine the biochemical and histologic parameters of the ligament/prosthetic complex at 6 months and 1 year. To determine the effect of an intra-articular prosthetic device on the articulating cartilage and surrounding synovial tissues within the knee.

(16) Technical Approach: Left stifle joint used as a control, arthrotoomy and rupture of the anterior cruciate ligament, the right knee underwent rupture of the anterior cruciate ligament and augmentation using the patella tendon with supplementation using an artificial ligament prosthesis.

(17) Progress: Due to restriction of dogs in research, the study was completed and the data is now being analyzed at Howmedica Lab.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/201 (3) Status: Completed  
(4) Title:

CT Diagnoses of Medical Meniscal Tears

(5) Start Date: 1983	(6) Est Compl Date: 1985
(7) Principal Investigator: Ricky Wilkerson, CPT, MC Walton W. Curl, LTC, MC Marlene J. Severson, CPT, MC	(8) Facility: FAMC
(9) Dept/Svc: Surgery/Orthopedic	(10) Assoc Investigators:
(11) Key Words: medial meniscus tears and CT scan	

(12) Accumulative MEDCASE: \* (13) Est Accum OMA Cost: \*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 3  
d. Total Number of Subjects Enrolled to Date: 8  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the possible usefulness in diagnosis of medical meniscal tears of the knee using the CT scan and to compare it to the accuracy of the knee arthrogram. Subject population will consist of approximately 15 adult patients who on physical examination have suspected medial meniscal tears.

(16) Technical Approach: Patients with suspected meniscal tears first underwent arthrogram followed by CT scan.

(17) Progress: The results are now being tabulated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/202 (3) Status: Terminated

(4) Title:

Microbiology of Eyebank Eyes Taken from Septic Donors

(5) Start Date: 1983

(6) Est Compl Date: Terminate

(7) Principal Investigator:

(8) Facility: FAMC

Andrew J. Cottingham, M.D.

(9) Dept/Svc: Surg/Ophthalmology

(10) Assoc Investigators:

(11) Key Words:

eye bank, septic, donor eyes  
corneal transplant

Douglas A. Freeley, LTC, MC  
Floyd M. Cornell, LTC, MC  
Ronald Holweger, MAJ, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15)

Suitable donor material for this project has not been available as anticipated. Terminate study.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/203 (3) Status: Completed

(4) Title: Laser Trabeculoplasty: Correlation of the Number of Laser Applications to Short- and Long-Term Effects

(5) Start Date: 1983

(6) Est Compl Date: 1984

(7) Principal Investigator:  
John A. McCubbin, CPT, MC  
William G. Carey, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc Surg/Ophthalmology

(11) Key Words:  
laser trabeculoplasty  
intraocular pressure  
trabecular meshwork

(10) Assoc Investigators:

Ronald Holweger, MAJ, MC  
Thomas Mader, MAJ, MC  
William Wilson, CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 4

d. Total Number of Subjects Enrolled to Date: 24

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". 0

(15) Study Objective: To correlate the number of laser burns applied during laser trabeculoplasty in patients with simple chronic open angle increase in intraocular pressure.

(16) Technical Approach: Patients will be followed during the immediate post-procedure period and closely monitored for complications and then followed for a period of one year at least to determine the long-term efficacy.

(17) Progress: Low-dose laser trabeculoplasty seems to be effective in the treatment of open angle glaucoma. Risks remain minimal as no complications have occurred.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/204 (3) Status: Completed  
 (4) Title: The Role of Minimal Surgical Debridement in the Treatment of Vesicant Extravasations

(5) Start Date: Sept 83	(6) Est Compl Date: Dec 84
(7) Principal Investigator: Timothy S. Loth, CPT, MC	(8) Facility: FAMC

(9) Dept/Svc: Surgery/Orthopedics	(10) Assoc Investigators:
(11) Key Words: extravasations vesicants debridement	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Object: The objective of this study was to define the role of minimal surgical debridement in the treatment of vesicant extravasations.

(16) Technical Approach: An animal model was employed to determine the efficacy of minimal surgical debridement on vesicant extravasations. Rats were injected bilaterally in the flanks with one side being operated on at various intervals while the opposite side was unoperated on and served as a control. Serial measurements of ulcer diameter up to 35 days after the vesicant injection were compared among the treatment groups and controls to determine the effectiveness of surgery in limiting ulcer size and in decreasing the number of persistent ulcers. Agents tested were doxorubicin, renograph and fluorescein.

(17) Progress: The study is now completed and awaiting publication in Cancer Treatment Reports.

**Presentations:**

Denver Children's Hospital Orthopaedic Day, April 26, 1984  
 Mid-Central States Orthopedic Society Resident's Award, June 1, 1984.  
 Hugh Mahon Lectureship Award, Denver, Colorado, June 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

- |   |   |
|---|---|
| (1) Date: 30 Sep 85 (2) Protocol WU#: 84/201 (3) Status: Ongoing  |   |
| (4) Title: Q-Switched Nd: YAG Laser in Discission of Secondary Membranes<br>(Device: Microruptor MR-2 Nd: YAG Laser; MFR: LASAG AG, Thun, Switzerland<br>Sponsor VTI, Inc, Torrance, CA |   |
| (5) Start Date: Feb 84  | (6) Est Compl Date:   |
| (7) Principal Investigator:<br>Douglas A. Freeley, COL, MC<br>Floyd M. Cornell, LTC, MC<br>Allan W. Berg, LTC, MC<br>Norman T. Byers, COL, MC   | (8) Facility: FAMC  |
| (9) Dept/Svc: Ophth/Surgery   | (10) Assoc Investigators:   |
| (11) Key Words:<br>YAG Laser  | Ricardo J. Ramirez, CPT, MC/Anthony R. Truxal, CPT,<br>Luis E. Colon, MAJ, MC<br>Michael J. Trynosky, CPT, MC<br>Michael W. Coatney, CPT, MC<br>Eric A. Cohn, CPT, MC |
| (12) Accumulative MEDCASE:*   | (13) Est Accum OMA Cost:*   |
| *Refer to Unit Summary Sheet of this report.  |   |
| (14) a. Date, Latest HUC Review: _____ b. Review Results: _____   |   |
| c. Number of Subjects Enrolled During Reporting Period: 85  |   |
| d. Total Number of Subjects Enrolled to Date: 85  |   |
| e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".     |   |
- (15) Study Objective: The overall purpose of this study is to determine the degree of safety and efficacy of the MR-2 Nd:YAG Laser manufactured by LASAG AG of Thun, Switzerland, in performing non-invasive intraocular surgery for discission of secondary membranes.
- (16) Technical Approach: Subjects will be chosen out of a candidate population of patients who are visually symptomatic from opacified secondary membranes but with healthy eyes. These candidates will be reviewed for contraindications to laser therapy. They will be in a state of health which will allow them to be able to sit at the laser surgical unit without discomfort. Patients entering the study will be given a preoperative evaluation including slit lamp microscopy and ophthalmoscopy.
- (17) Progress: To date 140 patients have been entered in the study. There have been no adverse effects and all patients treated have increased their visual acuity. We are continuing the manufacturer's protocol; however it is anticipated that the machine's use for this purpose will come off of core investigational status within the next six months. Once that occurs this study will be terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/200 (3) Status: Ongoing

(4) Title: Differential Fixation of Centrifuged and Non-Centrifuged  
Acrylic Bone Cement Specimens

(5) Start Date: 1985

(6) Est Compl Date:

(7) Principal Investigator:  
Joseph M. Wilson, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Surgery/Orthopedics

(10) Assoc Investigators:

(11) Key Words:

Joe K. Ozaki, COL, MC

acrylic bone cement

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to study volumetric change in acrylic cement as it is used in surgery with and without centrifugation; strength of bonding of acrylic cement to bone and to the prosthesis by "pull out" strength testing comparing cements with and without centrifugation and the variability of the shrinkage in the different types of acrylic cement available for orthopedic surgical use.

(16) Technical Approach: Acrylic bone cement will be mixed and changes recorded by direct and indirect (fluid displacement) methods. Model systems of initial/cement/bone will be tested to determine bonding strength of interface using a tensiometer.

(17) Progress: The orthopedic research lab has been set up and preliminary studies are actively ongoing.

Publications and Presentations: None

(1) Date: 30 Sep 85 (2) Protocol W#/: 85/201 (3) Status: Ongoing

(4) Title: Keratorefractive Surgical Techniques; Epikeratophakia, Keratophakia, and Keratomileusis; A Feasibility Study

(5) Start Date: 1985

(6) Est. Compl. Date:

(7) Principal Investigator:

(8) Facility: FAMC

Floyd M. Cornell, LTC, MC  
Michael J. Trynosky, CPT, MC

(9) Dept./Svr: Ophthalmology

(10) Assoc. Investigators:

(11) Key Words:

keratorefractive surgery

Margaret Lisecki, BS  
John A. McCubbin, CPT, MC  
Albert H. McCullen, CPT, VC

(12) Accumulative MEDCAPS: \*

(13) Est. Accum. OMA Cost: \*

\*Refer to Det. Summary Sheet of this report.

(14) a. Date, Date of Review: b. Review Result: \*

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: To determine if the animal species in question, New Zealand Albino Rabbit will demonstrate specific ophthalmological anatomical considerations to enable further research in keratorefractive surgery, comparing the effects of epikeratophakia, keratophakia, and keratomileusis in the correction of refractive errors.

(16) Technical Approach: New Zealand Albino Rabbits, 40 weeks of age or older will be used in this study. Rabbits will be studied to determine their body weight, corneal keratometry measurements, corneal thickness, corneal diameter, corneal curvature with a placido disc, intraocular pressures, refractive errors, ophthalmodynamometry measurements will be taken to determine which intraocular pressures that will not occlude the central retinal artery, and slit lamp examinations to detect the presence of absence of external eye disease. Rabbit will be anesthetized and eyes covered with a plastic drape to help maintain proptosis. A teflon adapter specifically designed to conform to the size and curvature of the rabbit globe is then placed over the eye of the rabbit and then the pneumatic ring of the microkeratome is placed onto the grooved anterior surface of the teflon adapter to allow for adequate transfer of suction to the rabbit's globe. With the teflon adapter and pneumatic suction ring in place, the base plate is fixed onto the microkeratome and the instrument is placed into the groove of the pneumatic pressure ring. The microkeratome is then engaged and slid smoothly across the cornea resulting in a lamellar resection. The button is then placed

## (16) Technical Approach: - Continued

onto the Delring base, stained, frozen and lathed to the appropriate dioptric power using the appropriate calculations for the specific keratorefractive procedure. Following cryolathing, the button, now referred to as a lenticule, is thawed and sutured onto the animals eye using 10-0 or 11-0 nonabsorbable nylon sutures. After all sutures have been placed an appropriate size therapeutic bandage contact lens will be applied followed by a 5-10mg subconjunctival gentamycin injection.

(17) Progress: No progress on this study has been made -- awaiting arrival of equipment.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/202 (3) Status: Ongoing	
(4) Title: NSABP Protocol C-02 A Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-Fluorouracil and Sodium Heparin in Patients with Resectable Adenocarcinoma of the Colon.	
(5) Start Date: 1985	(6) Est Compl Date:
(7) Principal Investigator: John F. McPhail, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Gen. Surgery Svc	(10) Assoc Investigators: Jerry E. Sims, M.D. Jeffrey R. Clark, M.D.
(11) Key Words: adenocarcinoma sodium heparin 5-fluorouracil	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: 0	
d. Total Number of Subjects Enrolled to Date: _____	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

(15) Study Objective: To determine the efficacy of perioperative portal vein infusion as an adjuvant therapy in patients with Duke's A, B, and C adenocarcinoma of the colon as compared to standard therapy which is surgery alone. The study is designed to determine whether there will be prolongation of the disease-free interval and increasing survivorship in patients undergoing curative resection of colonic adenocarcinomas and treated in this manner.

(16) Technical Approach: Patients will be assigned by random selection to one of the following groups: a) Surgery alone; b) Surgery plus additional continuous portal vein infusion with 5-FU 600 mg/M<sup>2</sup> and 5000 units sodium heparin per day, given for a total of 7 consecutive days. Portal vein catheters will be inserted intraoperatively after the colonic anastomosis has been completed. All portal vein infusions will be started within 6 hours of the operative procedure.

(17) Progress: This is a new study - no patients have been entered as of this APR date.

DEPARTMENT OF CLINICAL INVESTIGATION

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#:72/302 (3) Status: Ongoing

(4) Title: Comparison of Metabolic and Functional Changes in Defects of Platelet Function

(5) Start Date: 1972

(6) Est Compl Date:

(7) Principal Investigator:  
Donald G. Corby, COL, MC

(8) Facility: FAMC

(9) Dept./Svc: DCI/Biochemistry Svc

(10) Assoc Investigators:

(11) Key Words:  
platelet function  
newborn

T.P. O'Barr, Ph.D., DAC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/84 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: To correlate biochemical and functional parameters to gain a better understanding of the pathophysiology of the disorders of platelet function.

(16) Technical Approach: Platelet Function Studies: When indicated clinically, platelet counts, bleeding times, platelet adhesion, and whole blood and ADP aggregation in response to ADP, collagen, epinephrine, or ristocetin will be performed in the Coagulation Section, Department of Pathology or the Biochemistry Service, Department of Clinical Investigation. Biochemical Studies: Assessment of the content and release of the content of the platelet's subcellular storage organelles (alpha and dense granules) and evaluation of the platelet membrane will include, but not be limited to the following: a) Electron microscopy and mepacrine staining of dense granules; b) Content of platelet factor 4 and B-thromboglobulin activity in the alpha granules; c) Production of platelet-derived growth factor by <sup>3</sup>H-thymidine incorporation in 3T3 mouse fibroblasts by platelet lysates; d) Measurement of secretory acid hydrolases (B-glucuronidase, B-galactosidase and membrane P-nitrophenyl phosphatase) activities; e) Membrane glycoprotein and phospholipid content; f) Release of arachidonate from membrane phospholipids by phospholipase C and diglyceride lipase g) Mobilization of Ca<sup>++</sup>; h) Other studies as they become available.

(17) Progress: Work has begun on the evaluation of leucotrienes and other lipo-oxygenase pathway compounds during the past FY. Progress on protocol has been slowed because of the necessity to assign manpower to other clinical investigation protocols.

## Publications:

1. Corby, D.G., Shigeta, F.H., Greene, H.L. and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDI): Reversal with Total Parenteral Alimention (TPA). (Abst.) Clin. Res. 21:304, 1973.
2. Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P. and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. (Abst. P. 107), III Congress, International Society on Thrombosis Hemostasis (Vienna, Austria), June 1973.
3. Corby, D.G., (Intr. by Wm. E. Hathaway): Mechanism of Platelet Dysfunction in Newborn Infants. J. Ped. Res., Vol. 8, No. 4, April 1974.
4. Corby, D.G., Preston, K.A., O'Barr, T.P.: Adverse Effect of Gel Filtration on the Function of Human Platelets. Proceedings of the Society for Experimental Biology and Medicine, 146:96-98, 1974.
5. Corby, D.G., Putnam, C.W., Greene, H.L.: Impaired Platelet Function in Glucose-6-Phosphatase Deficiency. The J. Ped., 85:71-76, July 1974.
6. Corby, D.G., and Zuck, T.F.: Newborn Platelet Dysfunction: A Storage Pool and Release Defect. Thrombosis and Haemostasis, 36:200-207, 1976.
7. Corby, D.G., Goad, W.C., Barber, J. and O'Barr, T.P.: Evaluation of Cyclo-Oxygenase Pathway in Platelets of the Newborn. Thrombosis and Haemostasis (Stuttgart), 38:35, 1977 (Abstract).
8. Corby, D.G., O'Barr, T.P.: Decrease in  $\alpha$ -Adrenergic Binding Sites in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Blood, 52:161, 1978.
9. Corby, D.G.: Aspirin in Pregnancy: Maternal and Fetal Effects. Pediatrics, 62:930, 1978.
10. Corby, D.G., O'Barr, T.P.: Decreased  $\alpha$ -Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine. Dev. Pharmacol & Ther. 2:215-225, 1981.
11. Corby, D.G., O'Barr, T.P.: Neonatal Platelet Function: A Membrane-Related Phenomenon. Haemostasis, 10(4):177-232, 1981.
12. Corby, D.G., O'Barr, T.P.: Newborn Platelet Function. Chapter in Book "Acquired Bleeding Disorder in Childhood". Masson Publ, pages 31-37, 1981.
13. Corby, D.G., O'Barr, T.P. and Swanson, E.E.: Evidence for a Deficiency of Alpha-Granule Proteins in the Platelets of Newborn Infants. Soc. Ped. Res. May, 1983.

**Presentations:**

1. Corby, D.G., Shigeta, F.H., Greene, H.L., and Stifel, F.B.: Platelet Dysfunction in Glycogen Storage Disease Type I (GSDE): Reversal with Total Parenteral Alimentation (TPA). Presented: Western Society for Pediatric Research, Carmel, California, February 1973.
2. Corby, D.G., Preston, K.A., Shigeta, F.H., O'Barr, T.P. and Zuck, T.F.: Adverse Effect of Gel Filtration on the Adenine Nucleotides of Human Platelets. Presented: III Congress International Society on Thrombosis and Hemostasis, Vienna, Austria, June 1973.
3. Corby, D.G.: Mechanism of Platelet Dysfunction in Newborn Infants. Presented: Society for Pediatric Research, APS-SPR, Washington, D.C., May 1974.
4. Corby, D.G., Goad, W.C., Barber, J. and O'Barr, T.P.: Evaluation of Cyclo-oxygenase Pathway in Platelets of the Newborn. Presented: Vith International Congress on Thrombosis and Haemostasis, Philadelphia, Pennsylvania, June 1977.
5. Corby, D.G. and O'Barr, T.P.: Decreased - Adrenergic Receptors in Newborn Platelets: Cause of Abnormal Response to Epinephrine? Presented: VIith Congress International Society of Thrombosis and Haemostasis, London, England, 1979.

(1) Date: 30 Sep 85 (2) Protocol WU#: 77/300 (3) Status: Ongoing	
(4) Title: Immunologic Disorders in Children and Adults. I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies	
(5) Start Date: Oct 1977	(6) Est Compl Date: Open ended
(7) Principal Investigator: William J. Rickman, Ph.D. CPT, MS	(8) Facility: FAMC
(9) Dept/Svc: DCI/Immunology	(10) Assoc Investigators: Donald G. Corby, COL, MC
(11) Key Words: immunologic disorders	
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: Apr 85 b. Review Results: Ongoing	
c. Number of Subjects Enrolled During Reporting Period: 84	
d. Total Number of Subjects Enrolled to Date: 822	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: A clinical laboratory immunology consultative service has been in place since 1977. Main emphasis is on the design and evaluation of specialized immunologic procedures in support of diagnosis and management of patients presenting with disorders of an immunologic nature. Humoral evaluations are designed to characterize serum gamma-pathies through the use of serum protein electrophoresis, immunoelectrophoresis and immunoglobulin assessment. Urine evaluation is conducted to determine the severity of light chain disease when indicated. Cellular evaluation include the identification of cell populations that may be associated with the underlying cause of the immunodeficiency state. Lymphocyte phenotyping by flow cytometric procedures, quantitative mitogenesis, qualitative phagocytosis and chemotaxis assays are performed as indicated by clinical history. Patients are selected on the basis of severity of recurrent infection, clinical immunodeficiency state and/or failure of respose to medical management.

(17) Progress: During FY 85 six fellows from the Immunology/Allergy Service, Department of Medicine, were trained in laboratory immunology methods. A total of 84 patients were referred for immunologic evaluations; 18 humoral, 47 cellular and 15 combined humoral-cellular evaluations. Major findings included 5 cryoglobulinemias, 4 serum protein gammopathies (Two IgG Kappa, one IgA lambda and one IgA kappa) and one acquired B-lymphocyte deficiency. Twelve AIDS - suspected patients were evaluated with six presenting with T-cell lymphopenia and seropositivity to HTLV-III.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/303 (3) Status: Completed

(4) Title: Study of Sensitivity of Tumors to Chemotherapy

(5) Start Date: 1980

(6) Est Compl Date:

(7) Principal Investigator:  
Charles F. Ferris, CPT, MS  
Arlene J. Zaloznik, MAJ, MC  
Elder Granger, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI/Cell Physiology

(11) Key Words:  
chemotherapy  
in vitro, in vivo  
tumor cell

(10) Assoc Investigators:  
John W. Harbell, CPT, MS  
SP5 Norman R. Jones  
SP5 Leslie Kramer  
Donald B. Mercill, DAC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To perform in vitro chemotherapeutic sensitivity testing using tumor cell systems. b) to correlate in vitro chemotherapeutic sensitivity testing results with in vivo chemotherapeutic responses. c) to provide better patient care, ie, better tumor cell kill, by using in vitro chemotherapeutic sensitivity testing. d) to study alternative therapeutic regimes for various types of solid tumors using the cell lines produced in part a.

(16) Technical Approach: Human tumor cell lines are established in monolayer culture. After purification and cell type varification, replicate cultures are subjected to physiological concentrations of chemotherapeutic agents. Efficacy is determined through measurement of macromolecular synthesis labeling index and cell loss. Correlations between in vitro parameters and patient responses are then established.

(17) Progress: Due to transfer of primary investigator, the study is closed.

SERVICE: Cell PhysiologyDEPARTMENT of Clinical Investigation

1. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan, R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. (Abst) Proceedings of the American Association for Cancer Research 23:33, 1982.
2. Harbell, J.W. and DiBella, N.J.: Studies on the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. (Abst) Proceedings of the American Association for Cancer Research 23:226, 1982.
3. Harbell, J.W., Mercill, D.B., Jones, N.R. and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. (Abst) In Vitro 18(3):295, 1982.
4. Harbell, J.W., Papkoff, J.S. and Daniel, C.W.: Hormone Requirements of the Pregnancy-Dependent Mammary Tumor of GR/A Mice: An In Vitro Study. J Natl Cancer Inst 69(6):1391-1402, December 1982.
5. Harbell, J.W., DiBella, N.J., Jones, L.E., Kramer, L.C., and Mercill, D.B.: Assessment of Synergism Between Hyperthermia (HT) and Chemotherapy (CT) Against Human Melanoma Cell Lines In Vitro. Pro Amer Assoc for Can Res 24:310, 1983 (Abst).
6. Harbell, J.W., Mercill, D.B. and Woods, L.K.: Use of Athymic Nude Mice to Establish Human Tumor Cell Lines. In Vitro 19(3):275, March 1983.
7. Correll, L.L., Neilsen, L.N., Kelleher, P.J., Harbell, J.W. and Minden, P.: Enhanced Immunogenicity of Line-10 Guinea Pig Hepatocarcinoma Cells after Culture. Accepted for Publication in J Natl Cancer Inst, 1983.
8. Wang, V., Gutman, D., Harbell, J., and Moore, G.E.: A Unique Gastrointestinal Cell Line. In Vitro 20(3):246, 1984. (abs)
9. Wang, V., Gutman, D., Harbell, J., and Moore, G.E.: A Cell Line Established from Malignant Distal Renal Tubule Cells. In Vitro 20(3):247, 1984. (Abs)
10. Mercill, D.B., Jones, N.R., and Harbell, J.W.: Human Tumor Cell Destruction by Distilled Water: An In Vitro Evaluation. Cancer (in press).

SERVICE: Cell PhysiologyDEPARTMENT: of Clinical Investigation

1. Mercill, D.B., Jones, N.R., and Harbell, J.W.: Distilled Water Lavage to Kill Human Tumor Cells: an In Vitro Evaluation of a Traditional Surgical Technique. Presented: Society of Armed Forces Medical Laboratory Scientists Tri-services Annual Meeting, Reno, Nevada, March 1982.
2. Harbell, J.W. and DiBella, N.J.: Studies of the Interaction of Tetrahydrocannabinol (THC) with Chemotherapeutic Agents Against Human Tumors In Vitro. Presented: American Association for Cancer Research, St. Louis, MO, May 1982.
3. Moore, G.E., Harbell, J.W., Woods, L.K., Morgan, R.T., and Semple, T.U.: RPMI 8226, a Human Myeloma Cell Line: an Update. Presented: American Association for Cancer Research, St. Louis, MO, April 1982.
4. Harbell, J.W., Mercill, D.B., Jones, N.R., and Woods, L.K.: Establishment of a Human Leiomyosarcoma Cell Line. Presented: Tissue Culture Association, San Diego, CA, June 1982.
5. Harbell, J.W., DiBella, N.J., Jones, L.E., Kramer, L.C., and Mercill, D.B.: Assessment of Synergism Between Hyperthermia (HT) and Chemotherapy (CT) Against Human Melanoma Cell Lines In Vitro. Presented: American Association for Cancer Research, San Diego, CA, May 1983.
6. DiBella, N.J. and Harbell, J.W.: Interaction of Chemotherapy (CT) and Hyperthermia (HT). Presented: Triservices Medical Oncology Meeting, San Antonio, TX, 1983.
7. Harbell, J.W., Mercill, D.B., and Woods, L.K.: Use of Athymic Nude Mice to Establish Human Tumor Cell Lines. Presented: Tissue Culture Association Annual Meeting, Orlando, FL, June 1983.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 81/304 (3) Status: Completed  
 (4) Title: Ultrastructural and Immunological Aspects of In Vitro Interactions  
 Between Giardia lamblia Trophozoites and Host Leukocytes

(5) Start Date: Feb 82	(6) Est Compl Date: Completed
(7) Principal Investigator: Paul G. Engelkirk, LTC, MS Steven K. Koester, DAC	(8) Facility: FAMC
(9) Dept/Svc: DCI/Immunology	(10) Assoc Investigators:
(11) Key Words: <u>Giardia lamblia</u> <u>Leukocytes</u> <u>in vitro</u> interactions	Donald D. Paine, DAC Stanley L. Erlandsen, Ph.D. Samuel Roger Wetherill, III, LTC, MS

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: a) To determine the effects of anti-Giardia antibodies, complement and sensitized host cells on the phagocytosis and destruction of Giardia lamblia trophozoites in vitro. b) To determine the time frame in which host phagocytic cells attach to and phagocytose live Giardia trophozoites in vitro. c) To determine the host cell types that play a role in the phagocytosis of Giardia trophozoites in vitro.

(16) Technical Approach: Giardia lamblia trophozoites will be incubated with various combinations of host cells, anti-Giardia antibodies, and complement. Light microscopic, TEM and SEM observations will be made to determine the type and extent of host cell/parasite interactions under the various experimental conditions. In addition, Indium-labeled trophozoites will be used in cytotoxicity studies involving human peripheral blood leukocytes.

(17) Progress: During FY 85, experimentation was completed. Cumulative experiments have shown that: a) G. lamblia can be radiolabeled using Indium oxine and that human peripheral blood leukocytes are most cytotoxic in the presence of heat-labile serum components. b) Human peripheral blood eosinophils are capable of phagocytosing G. lamblia trophozoites in vitro and depositing eosinophil peroxidase onto the surface of these parasites. c) G. lamblia trophozoites are capable of activating complement. Data from these experiments have resulted in a total of six presentations at scientific meetings and three manuscripts published or submitted to scientific journals.

## Publications:

1. Engelkirk, P.G., Koester, S.K., Paine, D.D. and Erlandsen, S.L.: In Vitro Phagocytosis of Giardia Trophozoites by Rat Peritoneal Leukocytes: Light and Electron Microscopic Observations. Am J Anatomy (submitted).
2. Engelkirk, P.G., Paine, D.D., Koester, S.K. and Erlandsen, S.L.: A Method of Shipping Cell Monolayers on Glass Cover Slips for SEM. J of Electron Microscopy Technique (submitted).
3. Koester, S.K. and Engelkirk, P.G.: A Glass Cover Slip Technique for Studying In Vitro Interactions Between Giardia Trophozoites and Host Leukocytes by TEM SEM and Light Microscopy. J Parasitol 70:443-445, 1984.

## Presentations:

1. Koester, S.K., Engelkirk, P.G., Paine, D.D., Wuerz, D.J., and Rothlauf, M.V.: Influence of Anti-Giardia Antibody, Heat-Labile Serum Components, and Sensitized Host Cells on Short-Term In Vitro Interactions Between G. lamblia Trophozoites and Rat Peritoneal Leukocytes. Presented: Annual Meeting of the American Society for Microbiology, St. Louis, Missouri, March 1984.
2. Koester, S.K. and Engelkirk, P.G.: Glass Cover Slip Technique for Studying In Vitro Interactions Between Giardia Trophozoites and Host Leukocytes by TEM, SEM, and Light Microscopy. Presented: Rocky Mountain Branch of the American Society for Microbiology, Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984.
3. Engelkirk, P.G.: Of Eosinophils, Mast Cells and Parasites. Presented: Rocky Mountain Branch of the American Society for Microbiology, Summer Symposium on Host-Microbe Interactions, Pingree Park, Colorado, August 1984.
4. Paine, D.D., Wetherill, S.R. III, and Engelkirk, P.G.: In Vitro Cytotoxic Effects of Human Peripheral Blood Components on Giardia lamblia Trophozoites as Measured by Release of <sup>111</sup>Indium. Presented: Annual Meeting of the American Society for Microbiology, Las Vegas, Nevada, March 1985.
5. Paine, D.D., Engelkirk, P.G., Koester, S.K., and Erlandsen, S.L.: Use of A Glass Cover Slip Technique to Study Short-Term In Vitro Interactions Between Giardia lamblia Trophozoites and Human Peripheral Blood Eosinophils. Presented: Rocky Mountain Branch of the American Society for Microbiology, Estes Park, CO, September, 1985.
6. Paine, D.D., Engelkirk, P.G., Koester, S.K. and Erlandsen, S.L.: Use of a Glass Cover Slip Technique to Study Short-Term In Vitro Interactions Between Giardia lamblia Trophozoites and Human Peripheral Blood Eosinophils. Presented: Twenty-Fifth Interscience Conference on Antimicrobial Agents and Chemotherapy. Minneapolis, Minnesota, September 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/302 (3) Status: Ongoing	
(4) Title: The evaluation of recently introduced, commercially available clinical microbiology products for possible use in the FAMC diagnostic microbiology laboratory.	
(5) Start Date: 1 July 1982	(6) Est Compl Date: 1 July 1986
(7) Principal Investigator: Pari L. Morse Clifford Butler	(8) Facility: FAMC
(9) Dept/Svc: DCI/ Microbiology	(10) Assoc Investigators:
(11) Key Words: Diagnostic microbiology Microbiological products	None
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: May 85 b. Review Results: Ongoing	
c. Number of Subjects Enrolled During Reporting Period: NA	
d. Total Number of Subjects Enrolled to Date: NA	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").	

- (15) Study Objective:  
To evaluate recently introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within that laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.
- (16) Technical Approach:  
A separate protocol will be designed for each product evaluated.
- (17) Progress:  
A rapid method for the detection of group B Streptococcus antigen was evaluated during this year. This method utilized two currently available test kits, the Culturette Brand Ten-Minute Group A Strep ID System for the micronitrous acid extraction of test swabs, and the Welcogen Strep B for the group B latex antigen detection. Known cultures of group B Strep and other mixed flora were tested. Specificity and sensitivity for this testing procedure were 100% and 93%, respectively.

PRESENTATIONS FOR FY 85 Annual Progress Report

Proto No. 82/302

SERVICE Microbiology

DEPARTMENT DCI

- (1) Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented:
- (a) Uniformed Services Pediatric Seminar. Norfolk, VA. 2 March 1985
  - (b) 5th Annual Conference on Military Pediatrics Research. Aspen, CO. 15 July 1985.
  - (c) 14th Aspen Conference on Pediatric Research. Aspen, CO. 18 July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P. Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. Submitted to J Clin Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/301 (3) Status: Completed  
(4) Title: Evaluation of Psyllium Mucilloid: A Potential Trapping Agent  
for Ingested Solvents.

(5) Start Date: 1982	(6) Est Compl Date:
(7) Principal Investigator: Donald G. Corby, COL, MC Walter J. Decker, Ph.D.	(8) Facility: FAMC
(9) Dept/Svc: DCI	(10) Assoc Investigators:
(11) Key Words: psyllium mucilloid ingested solvents	A.H. McCullen, DV, CPT, VC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate 1) the stability of P/gel complexes in the GI tract of the laboratory animal, and 2) the ability of P to entrap solvents in vivo thus preventing their absorption and resultant systemic toxic manifestations and/or death.

(16) Technical Approach: The study will be conducted in 4 phases. Phases 1-3 will be experimental subjects (lab animals). The species will be determined from data derived from the literature concerning the known LD50 for ethylene glycol, methanol and kerosene (all commonly found in the home and can be easily swallowed), if available. If data is not available, studies of LD50 will be performed. Phase 4 will only be conducted if phases 1-3 show conclusively that P entraps solvents thus reducing systemic absorption, toxicity and death in lab animals. In phase 4, the subjects will be patients (adult or child) who present for treatment of acute iron intoxication at hospital emergency rooms or who contact poison treatment centers in five states. At that time an addendum covering the exact clinical protocol and human use requirements will be submitted to FAMC and IRC for approval to continue study.

(17) Progress: Phase 1-3 studies have been completed for methanol and ethylene glycol. Analysis and data indicates no difference in blood levels of these compounds between control rabbits and rabbits that received psyllium mucilloid (Kansyl).

**Publications:**

Decker, W.J., St. Claire, R.L., III, and Corby, D.G.: Psyllium Mucilloid: A Potential Trapping Agent for Ingested Solvents. International Congress of Clinical Toxicology, August 1982 (Abst).

**Presentations:**

Decker, W.J., St. Claire, R.L., III and Corby, D.G.: Psyllium Mucilloid: A Potential Trapping Agent for Ingested Solvents. Presented: 1982 International Congress of Clinical Toxicology, Snowmass, Colorado, August 1982.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/300 (3) Status: Terminated

(4) Title: Protein A as an Extracorporeal Immunotherapeutic Treatment  
for Canine Mammary Adenocarcinoma

(5) Start Date: 1984

(6) Est Compl Date: Terminate

(7) Principal Investigator:

(8) Facility: FAMC

Victor Feuerstein, DAC

Ian B. Stewart, CPT, MS

Nicholas Bethlenfalvay, M.D.

(9) Dept/Svc: DCI

(10) Assoc Investigators:

(11) Key Words:

canine mammary adenocarcinoma

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Protocol was never started due to the transfer of one of the principal investigators.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/301 (3) Status: Completed  
 (4) Title: Atropine Sulfate Administration in Sheep: Effects of Route of Administration and Hyperthyroidism on Pharmacokinetics

(5) Start Date: April 1985	(6) Est Compl Date: September 1985
(7) Principal Investigator: Pritam S. Verma, Ph.D. CPT, MS	(8) Facility: FAMC

(9) Dept/Svc: DCI/Biochemistry	(10) Assoc Investigators: Albert McCullen, CPT, VC Donald G. Corby, COL, MC Michael Perry, COL, MC Gerald S. Kidd, LTC, MC
(11) Key Words: atropine sulfate pharmacokinetics hyperthyroidism	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: N/A b. Review Results: Completed  
 c. Number of Subjects Enrolled During Reporting Period: 0  
 d. Total Number of Subjects Enrolled to Date: 0  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". No adverse drug reaction

(15) Study Objective: The first objective of the study is to determine the absorption, distribution and elimination kinetics of atropine sulfate in the sheep model after inhalation, intravenous, and intramuscular administration of the drug. The second objective is to study the pharmacokinetics of the drug in hyperthyroid sheep using intramuscular administration of the drug.

(16) Technical Approach: Fifteen female sheep, 8-12 months of age, are required for the study. The animals are fasted overnight prior to the study. Animals are sedated with intravenous ketamine hydrochloride before the catheterization in the study. Pulse rate, temperature and respiration are monitored every five minutes for the initial two hours of the study. Upon completion of the drug metabolism study, the animals are made hyperthyroid at which time the drug metabolism study is repeated using the intramuscular administration of the drug.

(17) Progress: This study has been completed. All the serum and urine samples generated by the study have been analyzed for the drug. The data will be fitted to an appropriate pharmacokinetic model using a computer program at FDA. It is expected that at least two presentations and two publications should arise from the study.

## PUBLICATIONS:

Kradjan, W.A., R.C. Smallridge and P.S. Verma. 1985 Atropine Serum Concentrations after Multiple Inhaled Doses of Atropine Sulfate. Clin. Pharmacol. Ther. 38:12-15.

## PRESENTATIONS:

1. Verma, P.S., A.J. Jackson, R.G. Adams and R.L. Miller, 1985 Radioimmunoassay of L-Hyoscyamine: Pharmacokinetic Application. Clin. Chem. 31:935.
2. Verma, P.S., Chadwick, W.W. and W.J. Georgitis. 1985. Effect of Castration and Sex Steroid Treatment on Serum Angiotensin Converting Enzyme Activity. 67th Annual Meeting of Endocrine Society, Baltimore, MD, Abstract #837.
3. Georgitis, W.J., T.L. Walden, G.S. Kidd and P.S. Verma. 1985. Effect of Castration and Testosterone on Serum Angiotensin Converting Enzyme Activity. 2nd Annual Army Regional American College of Physicians, San Francisco, CA.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/300 (3) Status: Terminated	
(4) Title: Production of Antibodies to Atropine, L-Hyoscyamine and Paralidoxime [2-PAM-Cl, 2- (hydroxyiminomethyl-1-pyridinium) chloride] in New Zealand White Rabbits	
(5) Start Date: July 1985	(6) Est Compl Date: Terminated, Aug 85
(7) Principal Investigator: Pritam S. Verma, Ph.D CPT, MS	(8) Facility: FAMC
(9) Dept/Svc: DCI/Biochemistry	(10) Assoc Investigators:
(11) Key Words:	Donald G. Corby, COL, MC
(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*	
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period:	
d. Total Number of Subjects Enrolled to Date:	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	
(15) Study Objective: To raise antisera to Atropine sulfate, L-Hyoscyamine and 2-PAM-chloride in New Zealand White rabbits.	
(16) Technical Approach: All the immunogens are prepared by using diazotization reaction and then directly conjugated to bovine serum albumin (BSA) to the tyrosine-histidine and tryptophan groups of BSA using the carbodiimide reaction. The rabbits are immunized with the drug BSA complex. Serum is tested for the presence of the antibody.	
(17) Progress: This protocol has been terminated due to the principal investigator leaving FAMC.	
Publications and Presentations: None	

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/301 (3) Status: Ongoing

(4) Title: Studies of the Antigen-specific Recognition Receptor on Human T Lymphocytes

(5) Start Date: July 1985 (6) Est Compl Date: June 1987

(7) Principal Investigator: William J. Rickman, Ph.D.  
CPT, MS (8) Facility: FAMC

(9) Dept/Svc: DCI/Immunology (10) Assoc Investigators:

(11) Key Words: t cell antigen receptor Joseph Lima, DAC, GS-11  
Ann Hoyt, DAC, GS-9  
Sheri Muehlbauer, DAC, GS-9  
Jeneen Nelson, DAC, GS-9

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: July 85 b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this study is to evaluate the structural and functional aspects of the thymus-derived lymphocyte (T-cell) antigen receptor on normal lymphocytes resulting from tetanus toxoid immunization.

(16) Technical Approach: Lymphocytes from healthy subjects with a history of DTP immunization and tetanus booster are cultured in-vitro in the presence of tetanus toxoid antigen preparations. Lymphocyte cultures are sampled for DNA content, HLA-DR, T3, T4, T8 and interleukin-2 receptor expression by flow cytometric evaluation. Cell cultures are enriched for antigen responding cells and subjected to long-term tissue culture cloning procedures. Lymphocyte membranes from responding clones are harvested for electrophoretic blotting analysis to characterize receptor molecules involved in antigen recognition.

(17) Progress: Five subjects have been enrolled in this protocol to date. Fifteen antigen challenge cultures have been performed providing the necessary data to initiate cloning experiments.

Publications and Presentations: None

DEPARTMENT OF OB-GYN

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/350 (3) Status: ongoing  
(4) Title: GOG Studies


(5) Start Date: 1980	(6) Est Compl Date: N/A
(7) Principal Investigator: Francis J Major, MD Chief, GYN Tumor Service Denver General Hospital	(8) Facility: FAMC George L Phillips COL,MC Chief, OB-GYN Dept
(9) Dept/Svc: OB-GYN Dept	(10) Assoc Investigators:
(11) Key Words: See attached list	N/A

(12) Accumulative MEDCASE:\* N/A (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

PLEASE SEE ATTACHED

(15) Study Objective:  
PLEASE SEE ATTACHED

  
GEORGE L. PHILLIPS, JR.  
COL,MC  
Chief, OB-GYN Dept

25 September 1985

SUMMARY OF PROTOCOL PROGRESS  
FOR ANNUAL PROGRESS REPORT FY 85

1. Please refer to "Summary of Protocol Progress for Continuing Review dated 31 Mar 85" on file with your office.
2. Since that report, one additional patient has been entered on Protocol 52 with no adverse reactions noted and clinical complete response to her chemotherapy.
3. Since summary of 31 Mar 85, two additional protocols have been submitted and approved by the IRC:

PROTOCOL 78: Evaluation of Adjuvant Vinblastine, Bleomycin and Cis-Platinum Therapy in Total Resected Choriocarcinoma, Endodermal Sinus Tumor, or Embryonal Carcinoma of the Ovary Pure and Mixed with Other Elements.

PROTOCOL 79: Single Agent Weekly Methotrexate (NSC# 740) Therapy in the Treatment of Nonmetastatic Gestational Trophoblastic Disease, Limited Access, Phase 2 Trial.

SUMMARY OF PROTOCOL PROGRESS

1. PROTOCOL 26:

Section A. Master Protocol for Phase II Drug Studies in the Treatment of Advanced Recurrent Pelvic Malignancies.

Section C. A Phase II Trial of Cis-Platinum. Closed to all, but first line therapy for uterine sarcomas and first line therapy for ovarian sarcomas. One patient entered, but expired at home before response could be evaluated.

Section D. A Phase II Trial of VP 16. Ongoing. One patient entered who has received one course. Too early to evaluate for response. No toxicity to date.

Section L. A Phase II Trial of Tamoxifen. Ongoing.

Section N. A Phase II Trial of DHAD. Ongoing.

Section O. A Phase II Trial of AZQ. Ongoing.

Section Q. A Phase II Trial of Aminothiadiazole. One patient entered without response. No significant toxicity noted.

Section R. A Phase II Trial of Progestin. Closed to patient accrual.

Section S. A Phase II Trial of VM26. Ongoing. Two patients entered, both with partial response and no significant toxicity.

Section T. A Phase II Trial of 4'-Deoxydoxorubicin. Study closed.

2. PROTOCOL 34: A Randomized Suty of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I and Occult Stage II. (Phase III closed) Ongoing.

3. PROTOCOL 40: A Clinical-Pathologic Study of Stages I and II Uterine Sarcomas. Two patients entered.

4. PROTOCOL 41: Surgical Staging of Ovarian Cancer. Closed to all, but germ cell and sex cord tumors of the ovary.

5. PROTOCOL 44: Evaluation of Adjuvant Vincristine, Dactinomycin and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor (Phase II). Closed to all, but immature teratomas.

6. PROTOCOL 45: Evaluation of Vinblastine, Bleomycin and Cis-Platinum in Stages III and IV and Malignant Germ Cell Tumors of the Ovary (Phase II). Ongoing.

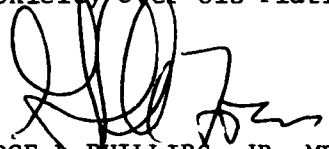
7. PROTOCOL 48: A Study of Progestin Therapy and a Comparison of Adriamycin Versus Adriamycin Plus Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure (Phase III). Ongoing.

## PROTOCOL PROGRESS

8. PROTOCOL 49: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix, Stage I-B and Randomly-Assigned Radiation Therapy Versus No Further Therapy in Selected Patients (Phase III). Closed to patient entry, but randomization portion re-activated 18 Apr 84.
9. PROTOCOL 52: A Phase III Randomized Study of Cyclophosphamide Plus Adriamycin Plus Platinol Versus Cyclophosphamide Plus Platinol in Patients with Optimal Stage III Ovarian Cancer. Ongoing.
10. PROTOCOL 54: The Treatment of Women with Malignant Tumors of the Ovarian Stroma with Combination VCR, Dactinomycin and Cytosan (Phase III). Ongoing.
11. PROTOCOL 55: Hormonal Contraception and Trophoblastic Sequelae After Hydatidiform Mole (Phase III). Ongoing.
12. PROTOCOL 57: A Randomized Comparison of Multi-Agent Chemotherapy with Methotrexate, Dactinomycin and Chlorambucil Versus the Modified Bagshawe Protocol in the Treatment of Poor Prognosis Metastatic Gestational Trophoblastic Disease (Phase III). Ongoing.
13. PROTOCOL 60: A Phase III Randomized Study of Doxorubicin and Cyclophosphamide and Cis-Platinum Versus Doxorubicin Plus Cyclophosphamide Plus Cis-Platinum Plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stages III and IV. Ongoing. Four patients entered with two complete responders and two partial responders. Only the usual hematologic toxicity noted.
14. PROTOCOL 61: A Phase III Randomized Study of Cis-Platinum Plus Cyclophosphamide Versus Hexamethylmelamine After Second Look Surgery in Non-measurable Stage III Ovarian Adenocarcinoma Partially Responsive to Previous Regimens Containing Cis-Platinum and Cyclophosphamide. Ongoing.
15. PROTOCOL 63: A Clinical-Pathologic Study of Stages II-B, III and IV, A Carcinoma of the Cervix. Ongoing.
16. PROTOCOL 64: A Randomized Comparison of Rapid Versus Prolonged 24 Hour Infusion of Cis-Platinum in Therapy of Squamous Cell Carcinoma of the Cervix, Phase III. Re-activated 21 July 1984.
17. PROTOCOL 66: Ultrastructural, Staging and Therapeutic Consideration in Small Cell Carcinoma of the Cervix (Phase II). Ongoing.
18. PROTOCOL 72: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and A Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease. Ongoing. One patient entered.
19. PROTOCOL 70: Randomized Comparison of Single Agent Chemotherapy, Methotrexate and Methotrexate with Folinic Acid Rescue, in Good Prognosis Metastatic Gestational Trophoblastic Disease (Phase III). Ongoing.

#### PROTOCOL PROGRESS

20. PROTOCOL 73: A Clinical-Pathologic Study of Primary Malignant Melanoma of the Vulva Treated by Modified Radical Hemivulvectomy. Ongoing.
21. PROTOCOL 74: Early Stage I Vulvar Cancer Treated with Ipsilateral Superficial Inguinal Lymphadenectomy and Modified Radical Hemivulvectomy (Phase III). Ongoing.
22. PROTOCOL 75: Postoperative Pelvic Radiation in Stages I and II Mixed Mesodermal Tumors of the Uterus (Phase III). Ongoing.
23. PROTOCOL 7602: Ovarian Cancer Study Group Protocol for All Stages I-C and II-A, B and C, Selected Stage IA-2 and IB-2. Suspended.
24. PROTOCOL 77: Chip Versus Carboplatin in Advanced/Recurrent Squamous Cell Carcinoma of the Cervix. Closed to patient accrual. Two patients entered with transient partial responses noted. Marked improvement in terms of toxicity over Cis-Platinum itself.



GEORGE D. PHILLIPS, JR., MD  
LTC(P), MC  
Chief, GYN & GYN-Oncology Service  
Asst C, OB-GYN Dept

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/351 (3) Status: Completed

(4) Title:

Danazol in the Treatment of Premenstrual Syndrome

(5) Start Date: 1983

(6) Est Compl Date: 1985

(7) Principal Investigator:

(8) Facility: FAMC

Albert P. Sarno Jr., CPT, MC

(9) Dept/Svc: OB/GYN

(10) Assoc Investigators:

(11) Key Words:

premenstrual syndrome  
danazol

Edward G. Lundblad, LTC, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review:

b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 20

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to perform a prospective double-blind, crossover study to determine if Danazol is more effective than placebo in treating reproductive age women with premenstrual syndrome.

(16) Technical Approach: Twenty five reproductive age women are to be studied in a double-blind, crossover study to determine the effectiveness of Danazol in premenstrual syndrome. The study is 4 months in duration, 2 months placebo, 2 months Danazol. Patients will take medication from the onset of symptoms to onset of menses. Symptoms will be evaluated with a menstrual symptom diary and results between treatment and placebo cycles will be analyzed statistically. In addition, levels of FSH, LH, progesterone, and estradiol will be obtained and evaluated.

(17) Progress: The study is now complete and the data is being analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

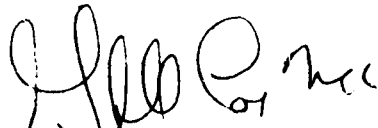
- |  |   |
|--|---|
| (1) Date: 30 Sep 85 (2) Protocol WU#: 84/350 (3) Status: ongoing   |   |
| (4) Title: A Prospective Randomized Study of the Effects of CO <sub>2</sub> Laser Vaporization of the Cervix for Cervical Intraepithelial Neoplasia on Cervical Factors and Subsequent Fertility |   |
| (5) Start Date: 1 Aug 84   | (6) Est Compl Date: 31 Jul 87                         |
| (7) Principal Investigator:<br>GEORGE L PHILLIPS, JR<br>COL,MC<br>Chief, OB-GYN Depart   | (8) Facility: FAMC                                    |
| (9) Dept/Svc: Dept of OB-GYN   | (10) Assoc Investigators:                             |
| (11) Key Words:<br>CO <sub>2</sub> Laser Vaporization<br>Cervical Intraepithelial Neoplasia<br>Fertility Effects   | EDWARD G LUNDBLAD<br>LTC,MC<br>C, Family Planning Svc |
| (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*  |   |
| *Refer to Unit Summary Sheet of this report.   |   |
| (14) a. Date, Latest HUC Review: _____ b. Review Results: _____  |   |
| c. Number of Subjects Enrolled During Reporting Period: _____  |   |
| d. Total Number of Subjects Enrolled to Date: _____  |   |
| e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".              |   |

No adverse effects have been noted

(15) Study Objective: To assess the impact, if any, of CO<sub>2</sub> laser vaporization of the cervix for cervical intraepithelial neoplasia upon cervical factors related to potential fertility and subsequent fertility impact, if any.

16) TECHNICAL APPROACH: Patients with the diagnosis of CIN who are candidates for laser vaporization of the cervix will undergo pre- and postvaporization postcoital tests and long-term follow-up of fertility.

17) PROGRESS: Four patients have been entered on this study to date since its inception. All suitable candidates for this protocol have consented to entry. The slow accrual is due to the lack of adequate numbers of patients who are utilizing either the IUD or no form of contraception and who have cervical intraepithelial neoplasia. Request continuation of this study.

  
GEORGE L PHILLIPS, JR  
COL,MC  
Chief, OB-GYN Department

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/351 (3) Status: Terminated  
 (4) Title: Prospective Study Topical Acyclovir vs CO2 Laser in 1<sup>o</sup> HSV

(5) Start Date: 1984	(6) Est Compl Date:
(7) Principal Investigator: Walter Jarrett, CPT, MC	(8) Facility: FAMC

(9) Dept/Svc: OB-GYN	(10) Assoc Investigators:
(11) Key Words: acyclovir co2 laser HSV	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:  
 N/A

(16) Technical Approach:  
 N/A

(17) Progress: Study never begun because of departure of principal investigator. Recommend termination.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/352 (3) Status: Ongoing  
 (4) Title: Characterization of Steroid Hormones Produced by Short-Term Incubation of Luteal Cells Obtained from Macaca Fascicularis with Induced Luteal Phase Defects

(5) Start Date: August 1985 (6) Est Compl Date: March 1986

(7) Principal Investigator: Edward Miller, CPT, MC  
 Charles F. Ferris, CPT, MS (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Assoc Investigators:

(11) Key Words: Donald G. Corby, COL, MC  
 Albert H. McCullen, CPT, VC  
 Edward Lundblad, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period:  
 d. Total Number of Subjects Enrolled to Date:  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: The objective is to determine if differences exist between control and luteal phase defect induced cycles in the short-term production of steroids significant during the mid-luteal phase of the menstrual cycle of monkeys. If differences exists, possible new therapy for specific types of infertility may be recommended.

(16) Technical Approach: Luteal cells are obtained 5-8 days post-ovulation by luteectomy. The luteectomy obtained cells are processed, then cultured for 3 hours. The supernatant will be assayed for pregnenolone, progesterone, 17PH progesterone and testosterone using RIA procedures. The differences in assay levels of the steroid production from the control and treated cells will be statistically measured using multiple means tests.

(17) Progress: Culture and production of steroid cells from the control cycle has nearly been completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/400 (3) Status: Terminated

(4) Title: The Effect of Glycerin Suppository Administration on  
Bilirubin Levels in Infants Receiving Phototherapy

(5) Start Date: 1982

(6) Est Compl Date: Terminated

(7) Principal Investigator:  
Gail Murphy, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Newborn

(11) Key Words:  
hyperbilirubinemia  
glycerin suppositories

(10) Assoc Investigators:

John R. Pierce, LTC, MC

Gerald B. Merenstein, COL, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether the utilization of glycerin suppositories to enhance stooling effects peak serum bilirubin or influences changes in bilirubin levels in infants 36 weeks gestational age being treated with phototherapy for hyperbilirubinemia.

(16) Technical Approach: Sixty infants 36 weeks gestation and 1 week of age who require phototherapy for treatment of hyperbilirubinemia will be studied. Infants will be randomly assigned to a treatment group of glycerin suppositories every 4 hours or a control group. Bilirubin levels will be determined every 6-8 hours while under phototherapy for treatment and control patients. Results will be tabulated and statistically evaluated for any benefit.

(17) Progress: Study is terminated.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/403 (3) Status: OnGoing  
(4) Title:

(5) Start Date: Nov 1982 (6) Est Compl Date: Indefinite  
(7) Principal Investigator: Askold D. Mosijczuk, M.D., LTC, MC (8) Facility: FAMC

(9) Dept/Svc: (10) Assoc Investigators:  
(11) Key Words: 82/403 Original POG Study  
Thomas Carter, COL, MC Neurosurgery Svc  
Jeffrey Clark, Col, MC, C, Surg, Svc  
William Daniel, MD, Radiation Oncology  
Vishnu Reddy, LTC, MC, C, Hematopathology  
Thomas Stocker, LTC, MC, C, Ped. Pathology  
(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\* Michael Edwards, CPT (P)  
\*Refer to Unit Summary Sheet of this report. MC, C, Chemo Pharmacy

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 5  
d. Total Number of Subjects Enrolled to Date: 23  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective. and (16) Technical Approach are contained in the protocols for the 24 POG/SWOG studies involved under WU #82/403.

(17) Progress: See attached sheet

DEPARTMENT OF PEDIATRICS

(17) Progress

In August 1985 the following 3 POG protocols were approved by IRB and should be added to "82/403 Original POG/SWOG Studies"

1. POG 8370 (B(c)14-DBD Dibromodulcitol in Children with Recurrent Solid Tumors and Brain Tumors Resistant to Standard Therapy, Phase III.
2. POG 8441 - Four Drug Chemotherapy for Children with Stage D Neuroblastoma Older Than 365 Days at Diagnosis, A Phase III Study.
3. POG 8451 - Intergroup Rhabdomyosarcoma Study III.

B(C) 89#1: POG #7376 Histiocytosis X Natural History.

Two patients with Histiocytosis X were entered on the study previously and are continued to be followed. Study has been closed by POG to new entries.

B(C) 89#2: POG #8047 Histiocytosis X in Bone.

No patients have been entered at FAMC since the study started in 1982. The study has been closed by POG to new entries on 20 January 84.

B(C) 89#3: (SWOG) POG 7896 Multimodal Therapy for the Management of Primary, Non-metastatic Ewing's Sarcoma of Bone, Pelvic and Sacral Sites Excluded. Study is closed to new patients entries. No patients have been entered at FAMC.

B(C) 89#4: (SWOG) POG 7895 Multimodal Therapy for the management of Primary, Non-metastatic Ewing's Sarcoma of Pelvic and Sacral Bones, (IESS) Phase III. Study is closed to new entries as of January 1983. No new patients have been entered at FAMC.

B118 ADN - POG 8370 (EU) 82/403	B118-10	OTMR
ALDRY AS Evaluation of Response and Further	Ped Hematol Svc	
Determination of Toxicity of	Dept. PED	(EU)
Dibromodulcitol (DBD) in Children		
with Recurrent Solid Tumors and Brain		
Tumors Resistant to Standard Therapy		
Phase II (Askold D. Mosijczuk, LTC, MC		
Ped/Hem/Svc, PED)		

One patient was entered on this study in the past fiscal year on emergency one time use basis. Patient expired 3 weeks later of underlying disease. (Metastatic Osteosarcoma) and is unevaluable because of short interval on treatment.

ALRDY ASG 82/403Ad - V(C) 114 POG 8303: Ped Hem/ PED B114AD OTMR  
SIMAL #3, Phase III

(Askold D. Mosijczuk, LTC, MC

GROUP CR = Oct

One patient was entered on the study in the past fiscal year with isolated testicular relapse while on initial maintenance chemotherapy for ALL. Patient is doing well, in apparent complete remission. Toxicity has been moderate to severe myelosuppression, not unexpected, requiring occasional transfusions of packed RBCs and one hospitalization for suspected sepsis.

B(C) 89#5: (SWOG) POG #8095 Multimodal Therapy of Metastatic Ewing's Sarcoma with Chemotherapy including Adriamycin, Vincristine, Cyclophosphamide, 5-Fluorouracil, Actinomycin-D Plus Irradiation and Surgery (if feasible) Intergroup Ewing's Sarcoma Study Phase III. Study has been closed by POG (18 Feb 83). No patients have been enrolled at FAMC.

B(C) 89#6: POG 8104/05 Comprehensive Care of the Child with Neuroblastoma: A Stage and Age-Oriented Study, Phase III.

One new patient has been entered on protocol in the past fiscal year (Nov 84).

One patient entered in 1981 has had recurrent disease and died. Study has been closed by POG (Dec 84).

B(C) 89#7: POG 8103 Hepatoma III, Treatment of Hepatoblastoma and Hepatocellular Carcinoma in Children with Surgery, Radiation, and Chemotherapy Phase III.

This study was withdrawn by principal investigator in Nov 82. Study has been closed by POG on 20 June 84.

B(C) 89#8: (SWOG) POG-8000 National Wilms' Tumor Study #2.

No patients have been entered at FAMC in the last fiscal year or since the study was approved on 5 October 1982.

B(C) 89#9: POG 7909 Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma, Phase III.

One medulloblastoma patient at FAMC is enrolled. Patient is currently in complete remission, 2½ years from diagnosis.

B(C)89#10: (SWOG) POG 7898 Intergroup Rhabdomyosarcoma Study (IRS)-II Study has recently being closed by POG.

Expected myelosuppression with one episode of septicemia has been noted in one patient at FAMC. Four children with rhabdomyosarcoma have been enrolled at FAMC in the past. One patient with rhabdomyosarcoma of the left pharyngeal muscles enrolled 2½ years ago has completed therapy 8 months ago and is in complete remission. Two previous children have completed treatment per protocol and are in complete remission in good health, although one child was ruled ineligible for study after pathology review. A recent patient with extra osseous Ewing's sarcoma with pulmonary metastases at diagnosis (Sep 84) is currently NCR on maintenance chemotherapy.

B(C)89#11: (POG PROTOCOL #7837) Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia.

On 12 May 1983, protocol was amended nationally to include all pediatric patients with Stage III and IV Non-Hodgkin's Lymphoma, lymphoblastic variety in addition to T cell ALL patients.

One patient with T cell ALL was enrolled at FAMC in Aug 84. He continues to do well in CR.

B(C)89#12: POG 7712 Comparison of Treatment Regimes for the First CNS Relapse in Children with Acute Lymphocytic Leukemia, CNS Leukemia Study #6, Phase III.

Study was closed by POG on 2 Nov 82. No patients entered at FAMC.

B(C)89#13: POG 7901 Rescue therapy for non-CNS Extramedullary Disease in Children with Acute Lymphoblastic Leukemia, Phase III.

No patients were enrolled at FAMC. Study has been closed by POG 20 Dec 84.

B(C)89#14: POG 8107 Multi-institutional Controlled Trial of Adjuvant Chemotherapy in the Treatment of Osteosarcoma, Phase III.

One patient has been enrolled at FAMC. Patient has died of metastatic disease. The study was recently closed by POG. The study showed that adjuvant chemotherapy clearly was of statistical benefit in children with osteogenic sarcoma.

B(C)89#15: POG (SWOG) #7612 MOPP + BLEO and A-COPP with IF RT in Stage III Hodgkin's Disease in Children.

Study was closed by POG on 20 October 1982 due to poor patient accrual. No patients were entered at FAMC:

B(C)89#16: POG #7905 A-COP+ for Non-Hodgkin's Lymphoma in Children. Study is closed. There were no FAMC enrollments.

B(C)80#17: POG #8035/36 Laboratory Subclassification and Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALINC#13).

One patient was transferred on protocol to FAMC from WRAMC and continues in study in CR. Five new patients have been entered on study at FAMC in 1984. All continue on study in CR. Toxicity has been tolerable and predictable. Preliminary survival figures are excellent. Elimination of cranial irradiation in standard risk patients has not resulted in decreased survival or increased incidence of CNS relapse.

B(C)89#18 SWOG Protocol#7799 Rare Tumor Registry.

Two patients with rare tumors have been registered at FAMC. One patient with superficial melanoma of the eye is doing well in CR. The other patient, a newborn with metastatic undifferentiated sarcoma of the face has died.

B(C)89#19: POG#8958 NWTS Long-term Followup Study. No patients have been entered at FAMC.

B(C)89#20: POG #8157 Multi-agent Chemotherapy with Adjuvant Whole-body Irradiation in Half-body Increments in Patients with Clinical Group IV Rhabdomyosarcoma.

One patient was enrolled at FAMC who relapsed and died. Study was closed by POG on 20 Apr 84.

B(C)89#21: SWOG (POG) #8022 Evaluation of Vindesine Twice Weekly Plus Prednisone and A Cross-over Study of Vindesine-Prednisone vs Vincristine Prednisone in Children with Acute Lymphoblastic Leukemia, Hodgkin's Disease and Non-Hodgkin's Lymphoma.

No patients have been enrolled at FAMC. Study was closed by POG on 20 Jul 83.

B(C)89#22: POG 8106 High-dose Cyclophosphamide/High-dose Methotrexate with Coordinated Triple Intrathecal Therapy for Stages III and IV Non-lymphoblastic Lymphoma, Phase III.

No patients have been enrolled at FAMC, to date.

B(C) 89#23: POG #8101 Acute Nonlymphocytic Leukemia (ANLL) in Children Phase III.

Treatment Arm 2 has been closed to future patient entry because of a lower remission-induction rate. One patient was enrolled at FAMC in the past fiscal year. Patient is currently in CR doing well.

B(C)89#24: POG #8156 Live Varicella Protocol.

No patients have been enrolled at FAMC. This study was closed by POG on 15 Nov 83 and was closed at FAMC by principal investigator on 25 April 1983.

# SUMMARY OF PROTOCOL PROGRESS

## II. Patients Enrolled in POG Studies at FAMC

	<u>Pt.'s Initials</u>	<u>Diagnosis</u>	<u>Study</u>
	L.P.	melanoma of eye	POG 7799 B(C)89#18
	J.H.	ALL	POG 8035/36 B(C)80#17
	J.P.	ALL	POG 8035/36 B(C)80#17
	D.I.	ALL	POG 8035/36 B(C)80#17
	C.B.	ALL	POG 8035/36 B(C)80#17
	G.H.	ALL	POG 8035 B(C)80#17
	S.K.	T-ALL	POG 7837 B(C)89#11
			POG 8035 B(C)80#17
	A.D.	undiff sarcoma	POG 7799 B(C)89#18
	D.D.	histiocytosis X	POG 7376 B(C)89#1
	F.B.	rhabdo	POG 7898 B(C)89#10
	M.A.	rhabdo	POG 7898 B(C)89#10
	K.C.	rhabdo	POG 7898 B(C)89#10
	L.H.	extra-osseous Ewing's	POG 7898 B(C)89#10
	D.W.	medulloblastoma	POG 7909 B(C)89#9
	D.B.	neuroblastoma	POG 8104/05 B(C)89#6
New	A.L.	neuroblastoma	POG 8104/05 B(C)89#6
	M.P.	ependymoma	POG 7621
	R.O.	rhabdo	POG 8157 B(C)89#20
	D.W.	osteosarcoma	POG 8107 B(C)89#14
New	D.W.	osteosarcoma	POG 8370 (EU) 82/403
New	A.B.	AML	POG 8101 B(C)89#23
New	E.O.	relapsed ALL	POG 8303 B(C)14-DBD
New	D.F.	brainstem glioma	POG 8495

SERVICE Pediatrics HematologyDEPARTMENT Pediatrics

## PRESENTATIONS

1. At the semi annual meeting of POG in St. Louis, MO in October of 1984, Dr. Mosijczuk presented the following 2 proposed protocols:
  1. Use of AZQ in Brain Stem Glioma - a Pilot Study to be used in the POG.
  2. Front-Loading Chemotherapy for Children with Increased Risk Medulloblastoma - Pilot Study to be used in POG.
2. At the semia annual POG meeting in Clearwater, Florida in March 1985, Dr. Mosijczuk presented the Increased Risk Medulloblastoma proposed pilot study to the group. It is anticipated that this protocol will be activated in the POG within the next few months.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/401 (3) Status: Ongoing  
 (4) Title: Prevalence of Endometriosis Externa in Adolescent Women Complaining of Severe Dysmenorrhea

(5) Start Date: 4 April 1983	(6) Est Compl Date: June 1986
(7) Principal Investigator: Mark E. Blaedel, LTC, MC Edward Lundblad, LTC, MC	(8) Facility: FAMC
(9) Dept/Svc: Pediatrics/OR-GYN	(10) Assoc Investigators: Jerald F. Dirks, Psy D.
(11) Key Words:  Endometriosis Dysmenorrhea	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: NA b. Review Results: NA  
 c. Number of Subjects Enrolled During Reporting Period: See below<sup>+</sup>  
 d. Total Number of Subjects Enrolled to Date: Same  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

1. An epidemiologic survey of young women will document the prevalence of symptomatic endometriosis externa in a middle class primary care population of adolescent women complaining of dysmenorrhea. This prevalence figure will tell the health care provider how alert he has to be to this condition.

2. Background biosocial data will be collected in hopes that certain distinctive historical markers will distinguish the young woman with secondary dysmenorrhea due to endometriosos from the patient with severe primary dysmenorrhea.

3. A registry of young women with endometriosis will be developed. In the future, trials of medication can be given to these young women to determine the therapy of greatest benefit. These women can also be followed for a prolonged period of time to determine the incidence of complications of endometriosis.

+Stage I NA  
 Stage II NA  
 Stage III 5

(16) Technical Approach: This retrospective stage of epidemiologic survey is designed to isolate by questionnaire those young women who might have endometriosis and subject them to laparoscopy.

(17) Progress: As of 30 September 1985, 5 patients on protocol have had laparoscopy.

Publications and Presentations: None.

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/402 (3) Status: Ongoing  
 (4) Title: B<sub>2</sub> Microglobulin as a Measure of Renal tubular Function in the Neonate

(5) Start Date: 1983	(6) Est Compl Date: 1986
(7) Principal Investigator: Ronald J. Protman, MAJ, MC	(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Nephrology	(10) Assoc Investigators: James Burkenbaugh, MAJ, MC Gail Murphy, CPT, MC Alan Robson, M.D. Director, Pediatric Nephrology, St. Louis Children's Hospi Michael Southgate, CPT, MC (Eisenhower AM
(11) Key Words:	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/84 b. Review Results: Approved  
 c. Number of Subjects Enrolled During Reporting Period: 4  
 d. Total Number of Subjects Enrolled to Date: 53  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of the study is to examine renal handling of low molecular weight proteins in the neonate at various gestational and post-partum ages who manifest evidence of normal or abnormal intrauterine environments. The protocol was modified last year to see the effects of other renal physiologic factors on the renal handling of B<sub>2</sub>M such as GFR, free water clearances etc. This year we will also add the serum assay of atriopeptin to this analysis as it has only become available in the past month. This will require no extra blood as it can be done by a RIA with only 50 mcl of serum which is usually available after the other tests have been run. No one has ever looked at atriopeptins in the newborn but it is likely that it is responsible for the diuresis seen in the first few days of life in the newborn and thus may be effecting B<sub>2</sub>M handling.

(16) Technical Approach: Patients are selected on admission to the newborn nursery for either the normal group or for a specific pathologic condition. After consent is obtained, a urine bag is placed. Two timed urine collections on days 1 and 3 of life for urine creatinine, B<sub>2</sub>M, sp<sub>diu</sub>, and glucose will be obtained to calculate FEB<sub>2</sub>M, FENa, Tmglucose, C<sub>H<sub>2</sub>O</sub>, re and urine flow rate.

## Technical Approach - continued

Blood will be obtained by heelstick at the same time that routine laboratory (hct on day 1 and PKU on day 3) studies are obtained. Blood will be analyzed for B2M, creatinine, sodium, glucose, and atriopeptin. (We have deleted the need for serum osm. as we can calculate this from the serum sodium and glucose) RIA will be perform the B2M and Atiopeptin determinations. Chemistry will perform the other tests. The amount of blood taken from these full term newborns will in no way cause clinical difficulties nor the need for transfusion.

(17) Progress: This protocol has been on hold for the most part in the past year due to miltiple factors. The most important of these being the construction project in the newborn nursery and the fact that CPT Rosie Gibbons was ill for a time and then has PCS'd. She was involved with much of the data gathering. Now that the construction project completed and a new chief of the newborn service who has a great interest in the completion of the protocol, I feel we will be able to continue this important study and request continued approval.

Publications: None

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/400 (3) Status: Terminated

(4) Title:

Whole Blood Viscosity Determination vs Age of Sample

(5) Start Date: 1984

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

James T. Berkenbaugh Jr., MAJ

Beverly Anderson, CPT, MC

(9) Dept/Svc:

(10) Assoc Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

To clearly define the time period in which blood viscosity measurements are reliable after sampling, and whether viscosity measurements are altered at all shear rates beyond this time period.

(16) Progress: Study was terminated.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/401 (3) Status: Ongoing  
(4) Title:

Neonatal Xanthine and Aminoglycoside Kinetics

(5) Start Date: May 1984	(6) Est Compl Date: June 1986
(7) Principal Investigator: M. Gaile Murphy, M.D., CPT, MC	(8) Facility: FAMC

(9) Dept/Svc: Pediatrics	(10) Assoc Investigators: Gerald B. Merenstin, M.D., COL, MC John R. Pierce, M.D., LTC, MC
(11) Key Words: Computer program Drug kinetics	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: First b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: None  
d. Total Number of Subjects Enrolled to Date: 22  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: To employ a Bayesian computer program to individualize xanthine and aminoglycoside drug dosing decisions.

(16) Technical Approach: Sixty infants in nursery who require xanthine or aminoglycoside therapy will be studied. Dosing decisions based on program predictions of pharmacokinetics will be analyzed for prediction accuracy.

(17) Progress: 21 preliminary patients receiving gentamicin have been studied. The computer predictions have made therapeutic decisions quicker and more accurate.

PRESENTATIONS: Murphy, M.G. & Peck, C: Revisions of gentamicin therapy with a Bayesian program. Presented: Aspen Conference on Perinatal Research, Aspen, CO, July 1984.

Murphy, M.G., Peck, C.C.: Revisions of Gentamicin Therapy with a Bayesian Computer Program. Presented: Triservices Pediatric Meeting, Norfolk, Virginia, March 85.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84-402 (3) Status: Ongoing  
(4) Title:

Hypertension in Adolescents

(5) Start Date: July 84 (6) Est Compl Date: July 86  
(7) Principal Investigator: (8) Facility: FAMC

V. Lugo-Miro, M.D. CPT, MC

(9) Dept/Svc: Peds/Adolescent Med (10) Assoc Investigators:  
(11) Key Words: R. J. Portman, M.D., MAJ, MC  
Hypertension  
Adolescents

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 7 Aug 85 b. Review Results: Approved  
c. Number of Subjects Enrolled During Reporting Period: 510  
d. Total Number of Subjects Enrolled to Date: 1355  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective:  
Establish normal blood pressure values for height and weight rather than by age.

(16) Technical approach: For all patients visiting our clinic we will record age, height, weight, race, sex, Tanner stage of sexual development. Then will proceed to measure first, fourth and fifth Korotkoff sounds for blood pressure on right arms of seated individuals. For those that consent, body fat determinations are also recorded.

(17) Progress: We have enrolled in our study 1355 patients and we expect this year to achieve at least 1500 or more patients so that we can start looking at tabulating our results. However we are now on the process of writing up an abstract to be submitted for presentation in few pediatric research meetings. Abstract will be based on preliminary data available. Our goal will be then finish our study by the time it will be due for formal presentation if accepted.

Publications: None

Presentations: Abstract submitted for presentation or poster display at the Society for Adolescent Medicine Scientific meeting to be held at Baltimore, MD March 14-16, 1986. Waiting for their reply.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/403 (3) Status: Ongoing

(4) Title: Hypercalciuria in Children with Isolated Hematuria

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:  
Ronald J. Portman, MAJ, MC

(8) Facility: FAMC  
University of Colorado Health Science  
Center-Southwest Pediatric Nephrology  
Group

(9) Dept/Svc: Pediatrics/Nephrology

(10) Assoc Investigators:

(11) Key Words:  
hypercalciuria  
hematuria

Gary M. Lum, Renal Division, University  
of Colorado Medical Center

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: To determine the incidence of hypercalciuria in children presenting with isolated gross or microscopic hematuria. To determine if hypercalciuria is due to a) idiopathic renal calcium wasting, b) intestinal hyperabsorption of calcium or c) hyperparathyroidism.

(16) Technical Approach: Patients who are found to have hematuria, but without protein in the urine, will have a twenty-four urine collection for calcium excretion and a blood test for calcium. If these studies are normal, no further studies will be performed. If calcium secretion is abnormal, the patient will be placed on a specific low calcium diet for one week and then another twenty-four urine collection for calcium repeated. After this is completed, the child will have a calcium challenge test consisting of an oral calcium supplement and a specific breakfast high in calcium. Four-hour urine collections will follow this calcium load and a blood test for parathyroid hormone levels. Also, an intravenous pyelogram will be obtained to be sure the patient does not have kidney stones or other urinary tract abnormalities.

(17) Progress: No patients encountered to enter into study as yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/400 (3) Status: Completed  
 (4) Title: Sport-Specific Preparticipation Physical Examinations: A Viable Alternative To The Assembly Line "Routine" School Physical

(5) Start Date: 18 Jan 85	(6) Est- Compl Date: 12 Sep 85
(7) Principal Investigator: Ronald E. Persing Maj, USAF, MC	(8) Facility: FAMC

(9) Dept/Svc: Pediatrics/Adolescence	(10) Assoc Investigators:
(11) Key Words: Sports Medicine Injuries, Sport. Body Fat Preparticipation Evaluation	David W. Wells COL, USA, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 300  
 d. Total Number of Subjects Enrolled to Date: 300  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None

(15) Study Objective:

1. Provide a detailed preparticipation sports evaluation in the primary care setting in an expeditious manner.
2. Investigate injury patterns as they relate to specific sports.
3. Determine the percent body fat of study participants and recommend ideal playing weight for their sport.

(16) Technical Approach:

Three hundred preparticipation sports evaluations were completed. The evaluation began with a self administered questionnaire to identify past medical problems and previous musculoskeletal injuries. The physician then reviewed the positive responses with an indepth assessment of injury patterns in specific sports. The physical examination included evaluation of orthopedic function. Skinfold thickness was determined using a Lange skinfold caliper.

## (17) Progress:

The required 300 preparticipation physical evaluations have been completed. The percent body fat has been determined for each participant and they have received a written summary of their physical development, including their percent body fat and recommendation for ideal playing weight. Data on injury patterns of specific sports are presently being compiled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/401 (3) Status: OnGoing  
 (4) Title: Evaluation of Adrenocorticotrophic Hormone (ACTH) in the Prevention of Cancer Chemotherapy Induced Nausea and Vomiting in Children

(5) Start Date: March 85	(6) Est Compl Date: March 1987
(7) Principal Investigator: Askold D. Mosijczuk, M.D., LTC, MC Chief Ped. Hematology/Oncology Section	(8) Facility: FAMC
(9) Dept/Svc: Ped Hematology	(10) Assoc. Investigators: Michael Shull, MD, CPT, MC Kenneth Beougher, MAJ, MSC Michael Edwards, CPT (P) MSC
(11) Key Words: Evaluation of Adrenocorticotrophic Hormone in Chemotherapy Associated Nausea and Vomiting	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 0 at FAMC, 2 at Brooke AMC  
 d. Total Number of Subjects Enrolled to Date: 2  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: 1. Evaluate the effectiveness of ACTH in decreasing nausea and vomiting in children undergoing cancer chemotherapy. 2. Evaluate the toxicity of ACTH and thorazine in this setting.

16. Study Design: This will be a multi-center, double blinded, randomized, cross-over study with patients serving as their own control. Patients undergoing at least 2 courses of identical cancer chemotherapy will be randomized at the beginning of the study to receive either of 2 combinations of antiemetics.

1. ACTH with thorazine, or
2. placebo with thorazine

Patients will then receive the other combination prior to their next course of chemotherapy. Extent of nausea, vomiting, side effects, and patient preference will be measured and compared between the 2 combinations of antiemetics.

17. Progress: To date only two patients have been enrolled on study. In one patient one regimen was found to be markedly superior to the other one. Because of the blinded nature of this study, it is not known which of the two combinations of antiemetics appeared to be the more effective one. Study is otherwise progressing satisfactorily.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85-402 (3) Status: Ongoing

(4) Title:

Naloxone Therapy of Streptococcal Sepsis in a Suckling Rat Model

(5) Start Date:

(6) Est Compl Date: June 1986

(7) Principal Investigator:

(8) Facility: FAMC

M. Gail Murphy, M.D., CPT, MC

(9) Dept/Svc: Pediatrics

(11) Key Words:

Naloxone  
Sepsis

(10) Assoc Investigators:

Gerald B. Merenstein, M.D., COL, MC  
James T. Berkenbaugh, M.D., MAJ, MC  
Timothy Bonsack, M.D., CPT, MC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: First b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 400 Rats

d. Total Number of Subjects Enrolled to Date: 400 Rats

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

N/A

(15) Study Objective: Study the effect of Naloxone on survival in an animal model of Group B strep.

(16) Technical approach: Survival of those infected animals treated with intraperitoneal Naloxone is compared to those not treated.

(17) Progress: When an LD<sub>25</sub> Naloxone improved survival. When an LD<sub>50</sub> was given, no statistical difference in survival.

Publications: None

Presentations:

Murphy, MG, Pierce, JR, Berkenbaugh, JT, Merenstein, GB: Naloxone Therapy of Streptococcal Sepsis in a Suckling Rat Model. Presented: COMPRA, Aspen, Colorado July 1985.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/403 (3) Status: Ongoing  
 (4) Title: The Effects of L-Thyroxine on Acute Renal Failure

(5) Start Date: 1985	(6) Est Compl Date:
(7) Principal Investigator: Ronald Portman, MAJ, MC Brian Carter, M.D. Mark Gaylord, M.D.	(8) Facility: FAMC Denver Children's Hospital University of Colorado Health Sciences Center, Denver, CO
(9) Dept/Svc: Pediatrics	(10) Assoc Investigators:
(11) Key Words: renal failure l-thyroxine	Gary Lum, M.D. Rob Slover, M.D. Gerald Merenstein, M.D. Gail Murphy, M.D. Mario Eyzaguirre, M.D.

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) To study the effects of thyroid hormone on ameliorating the severity and complications of acute tubular necrosis (ATN) versus a control placebo-treated population with the same severity of ATN in a double blinded controlled fashion; b) To study the natural history of ATN in children in an intensive manner; c) To study the natural history of neonatal asphyxia, to retrospectively establish criteria for the severity of neonatal asphyxia and to apply these criteria prospectively to validate this scoring system, and d) To study the effects of asphyxia on the neonatal kidney.

(16) Technical Approach: Three groups of patients will be examined in this study. The first for patients with acute tubular necrosis with pediatric patients of all ages; the second for neonates with perinatal asphyxia. The adults patients will be divided into two groups, non-oliguric defined as urine output greater than 400 cc's per day, and oliguric defined as less than 400 cc's per day. These two groups will be similar to the pediatric groups of 1,2, and 3, mild, moderate, and severe ATN, respectively. Modification requested is in a blind randomized fashion. L-Thyroxine in a dose of 200 mcg. per meter squared per day vs. placebo vs. L-Triiodothyronine in a dose of 50 mcg per meter squared per day. For pediatric and neonatal patients, once the diagnosis of acute renal failure has been made and the baseline laboratories have been obtained the patient will be assigned to one of three categories based on the severity of the renal failure. GFR will be estimated in children greater than 1 year old by the formula:  $GFR (cc/min/1.73m^2) = (.ff) (height \text{ in cms})/plasma \text{ cre}(mg/dl)$ . GFR for an infant less than 1 year old will be estimated by the same formula except the constant is .45 instead of .55.

## (16) Technical Approach - continued

We will also compare our data to weight corrected GFR but not in the categorization phase. The patient after being placed in the appropriate category will be randomized to receive thyroid or placebo in a double blinded fashion. The next patient to enter this group will be paired with the first patient and given the alternate medication again in a blinded fashion.

(17) Progress: This is a new study which has just begun.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/404 (3) Status: Ongoing  
 (4) Title: Rapid Identification of Group B Beta-hemolytic Streptococci  
 by Direct Swab Micronitrous Acid Extraction Technique: Clinical Application

(5) Start Date: 23 July 1985	(6) Est Compl Date: Ongoing
(7) Principal Investigator: Stephen N. Nelson, M.D. Major, Medical Corps	(8) Facility: FAMC Fitzsimons Army Medical Center

(9) Dept/Svc: Newborn Svc/Dept Peds	(10) Assoc Investigators: Vicki Light, M.D., Cpt, MC John R. Pierce, M.D., LTC (P), MC Gerald B. Merenstein, M.D., COL, MC Richard O. Jones, M.D., LTC, MC Pari Morse, B.S., Sandra Tessies, DAC
(11) Key Words: Rapid identification Group B Streptococcus	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost: \*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 80  
 d. Total Number of Subjects Enrolled to Date: 80  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objective of this study is to determine the sensitivity, specificity, positive and negative predictive value and accuracy of the rapid identification technique as compared to standard culture techniques using highly selective media for group B beta-hemolytic streptococci (GBS) in antepartum women.

(16) Technical Approach: Four swabs (two swabs from vagina and two from cervix) are obtained during routine pelvic examination from each consenting patient. One swab from each site is transported in selective broth and plated the same day. Remaining swabs are transported in modified Amies transport media and subjected to the rapid I.D. procedures. These results are compared to those of standard culture.

(17) Progress (FY 85): Using the original technical approach, sensitivity and specificity were unacceptably low. The approach was revised thereafter with selective transport broth substituted for the Amies media. Within eighteen hours' incubation prior to identification by latex agglutination, sensitivity and specificity were 100%. However, since rapid identification is the goal of this study, we are currently attempting to employ the micronitrous acid extraction step more effectively and reduce the required incubation time.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/405 (3) Status: Ongoing  
 (4) Title: Blood and Marrow Neutrophils in Experimental Group B Streptococcal Sepsis: The Effects of Indomethacin and Naloxone.

(5) Start Date: July 1985	(6) Est Compl Date: November 1985
(7) Principal Investigator: James T. Berkenbaugh, Jr. Major, Medical Corps	(8) Facility: FAMC

(9) Dept/Svc: Pediatric/Newborn	(10) Assoc Investigators:
(11) Key Words: Blood and Marrow Neutrophils Group B Strep Sepsis Indomethacin Naloxone	Vishnu V. B. Reddy, LTC, MC Paul Simon, CPT, MC Stephen Nelson, MAJOR, MC Gerald B. Merenstein, COL, MC Arkold D. Mosieczuk, LTC, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: 99  
 d. Total Number of Subjects Enrolled to Date: 99  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective:

- (1) Determine if buffy coat smears reflect the status of the marrow neutrophil storage pool.
- (2) Study the effects of Indomethacin and Naloxone in blood and marrow neutrophil kinetics.

(16) Technical Approach:

Experimental Group B Streptococcal Sepsis is induced by SC inoculation of newborn rats at 3-4 days of age. Group of animals are sacrificed at 2, 6, 20 and 24 hours. Blood is obtained from the jugular vein for WBC, peripheral smear, buffy coat and differential. Bone marrow is obtained from the tibia or femur, and neutrophil proliferative and storage pools determined.

(17) Progress:

In Fiscal Year 1985 the majority of progress was made by overcoming the technical problems of obtaining blood and bone marrow from newborn rats, as well as determining an appropriate dose of Group B Streptococcus. At present, we are analyzing the data from 45 animals who received either saline control, or Indomethacin at the time of inoculation with Group B Strep.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/406 (3) Status: Ongoing  
(4) Title: Live Varicella Vaccine in Healthy Children in a Day Care Center

(5) Start Date: 1985	(6) Est Compl Date:
(7) Principal Investigator: James D. Arthur, COL, MC	(8) Facility: FAMC
(9) Dept/Svc: Dept of Pediatrics	(10) Assoc Investigators:
(11) Key Words: varicella vaccine	Myron Levin, M.D, UOCHSC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date:  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this study is (1) to evaluate the clinical and serologic responses to live attenuated varicella vaccine compared to placebo in susceptible healthy children in a day care center, and (2) to see if transmission of the vaccine virus occurs among susceptible and immune contents of the vaccines.

(16) Technical Approach: Children will be randomized under code to receive either varicella vaccine or placebo. Half of the children (Group 1) will receive vaccine on Day 0. The other children (Group 2) will receive placebo and will act as controls for a 6-week period and receive vaccine afterwards. Participants in Group 1 will be followed clinically for 42 days after vaccination; children in Group 2 will be followed for the 42 days when they act as controls and the 42 days after vaccination. The study population will consist of approximately 40-50 normal, healthy children, 1-10 years of age who attend a day care center.

(17) Progress: Study is new and as of this date no progress has been made. Recruitment letter has been sent out and we expect to proceed shortly.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/450 (3) Status: Ongoing  
(4) Title: Carticostoid Enhanced Plateletpheresis--A Feasibility Study

(5) Start Date: Nov 84	(6) Est Compl Date: Feb 86
(7) Principal Investigator: B.Vishnu V. Reddy, LTC, MC	(8) Facility: FAMC

(9) Dept/Svc: Dept Pathology	(10) Assoc Investigators: Willis Rieker, CPT, MC Rick E. Martinez, MT Judy Barber, MT (ASCP) Patricia Rush MT(ASCP)
(11) Key Words: plateletpheresis carticostoid enhancement with yield	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
d. Total Number of Subjects Enrolled to Date: \_\_\_\_\_  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

To obtain increased yield of platelets during "plateletpheresis"

(16) Technical Approach: N/A

(17) Progress: Study is pending the modification of "Donor" consent form.

Publications and Presentations: None

DEPARTMENT OF RADIOLOGY

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/602 (3) Status: Ongoing  
(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59)  
for Adrenal Evaluation and Imaging.

(5) Start Date: 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Peter W. Blue, LTC, MC	(8) Facility: FAMC

(9) Dept/Svc: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Iodocholesterol Adrenal	

(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	

(14) a. Date, Latest HUC Review: 11/84	b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:	0
d. Total Number of Subjects Enrolled to Date:	3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.	

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medula.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect the thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicure dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: No patients evaluated in the last 12 months. Test helpful in general.

Publications/Presentations: None.

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CLINICAL INVESTIGATION PROGRAM ANNUAL PROGRESS REPORT  
(U) FITZSIMONS ARMY MEDICAL CENTER AURORA CO D G CORBY  
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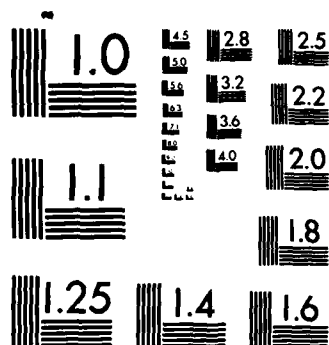
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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 82/602 (3) Status: Completed  
 (4) Title: Gallium Index: Qualitative vs. Quantitative Analysis

(5) Start Date: July 1983 (6) Est Compl Date: 1985  
 (7) Principal Investigator: (8) Facility: FAMC

Peter W. Blue, LTC, MC

(9) Dept/Svc: Nuclear Medicine Svc (10) Assoc Investigators:

(11) Key Words:

Gallium Index

Nasser Ghaed, COL, MC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/84 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 30

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: To evaluate a computer quantitative assessment of gallium uptake in normal and abnormal lungs and compare it to a previously used qualitative method.

(16) Technical Approach: All gallium studies are acquired on computer and pulmonary functions acquired. The gallium index is calculated both ways (vide supra) and when enough patients seen, data analyzed.

(17) Progress: Data collection completed. Results pending.

Presentations/Publications: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/601 (3) Status: Ongoing  
(4) Title: Evaluation of Indium Oxine In-111 Labeled Cellular Blood Components

(5) Start Date: 1 Oct 83	(6) Est Compl Date: 1987
(7) Principal Investigator: Peter W. Blue, LTC, MC	(8) Facility: FAMC

(9) Dept/Svc: Nuclear Medicine Svc	(10) Assoc Investigators: Nasser Ghaed, COL, MC
(11) Key Words: Indium Oxine	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 11/84 b. Review Results: Ongoing  
c. Number of Subjects Enrolled During Reporting Period: 8  
d. Total Number of Subjects Enrolled to Date: 8  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None.

(15) Study Objective: To evaluate Indium Oxine Labeled Blood Components and their metabolic fate, currently labeled WBC in infection.

(16) Technical Approach: Blood components (currently WBC are removed from patient, labeled, reinjected, and patient is scanned (labeled WBC will localize the infection sites).

(17). Progress: 8 abnormals.  
12 normals.  
Test is useful.

Presentations/Publications: None.

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/600 (3) Status: COMPLETED

(4) Title:

Prospective Study of the Effects of Diagnostic Ultrasound on the Human Auditory Mechanism Following in Utero Exposure

(5) Start Date: February 1984

(6) Est Compl Date: June 1984

(7) Principal Investigator:

(8) Facility: FAMC

Marlene J. Severson, M.D., CPT, MC

Gloria Hubred Komppa, M.D.

Jeffrey Davies, PHD, CPT, MSC

Fred Garner, M.D., CPT, MC

James Potter M.D., CPT, MC

(9) Dept/Svc: Radiology/Ultrasound

(10) Assoc Investigators:

(11) Key Words:

Nasser Ghaed, M.D., COL, MC

John Kolmer, M.D., COL, MC

Diagnostic Ultrasound, Biological Effects, Human Auditory Mechanism

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 100

d. Total Number of Subjects Enrolled to Date: 300

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

N/A

(15) Study Objective:

To determine whether children exposed (to diagnostic ultrasound) in utero have detectable hearing loss as compared to a non exposed population.

(16) Technical Approach: Pregnant women are being randomized into two groups. The control group is not receiving obstetric ultrasound. Family, birth and post natal histories are being collected on all study participants. Ultrasound data is collected on all women receiving it. Three to four months following delivery, the infants will be examined and audiological tests performed. The data will be compared.

(17) Progress: To date, 1985, obstetric ultrasound data was collected on approximately 300 patients. Approximately 200 patients were contacted. 22 patients had ENT examination and audiological testing. Three of the twenty-two patients were eliminated from the study due to abnormal ENT exam or neonatal history of meningitis. Of the remaining 19 patients, all exposed in utero, all had normal testing as compared to normative curves published in the 1960's prior to extensive use of diagnostic obstetrical ultrasound. This study has been completed and the data is to be submitted for publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/601 (3) Status: ONGOING	
(4) Title: An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease	
(5) Start Date: 10 Sept 84	(6) Est Compl Date: 1 Jan 87
(7) Principal Investigator: Maj Kenneth D. Hopper, M.D. LTC Louis F. Diehl, M.D. Maj Elder Granger, M.D.	(8) Facility: FAMC WRAMC
(9) Dept/Svc: Rad & Hem/Onc	(10) Assoc Investigators: May Lesar, M.D. Maj Todd Johns, M.D. Maj John Buaman, M.D. Maj Mark Ellis, M.D.
(11) Key Words: Computed Tomography Hodgkin's Disease	
(12) Accumulative MEDCASE:* *Refer to Unit Summary Sheet of this report.	(13) Est Accum OMA Cost:*
(14) a. Date, Latest HUC Review: _____ b. Review Results: _____	
c. Number of Subjects Enrolled During Reporting Period: 19 (FAMC & WRAMC)	
d. Total Number of Subjects Enrolled to Date: 59	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	

NONE

- (15) Study Objective:  
To evaluate the routine use of chest CT/C in the initial staging and evaluation of patients with newly diagnosed Hodgkin's Disease.
16. All patients newly diagnosed with Hodgkin's Disease both at FAMC and at WRAMC are requested to enter the study. If they agree, a chest CT will be obtained, even if there is a normal chest X-ray. The chest X-ray is evaluated using Form A by one investigator (ML) without knowledge of the CT. The Chest CT is evaluated by one investigator (KH) with the use of the chest X-ray. The results are entered on Form B. The two forms are compared and compared to the patients clinical data on Form C.
17. The results of 59 patients demonstrates the superiority of CT in delineating the various nodal chains involved in the mediastinum and to determine parenchymal/pleural/pericardial involvement. The clinical stage is changed because of the CT in a significant number of patients. However, the additional information does not seem to cause a treatment change in these patients. Only one in 59 patients has had a treatment change because of the CT.

**PRESENTATIONS**  
**PUBLICATIONS for FY 85 Annual Progress Report**

Proto No. 84/601

**SERVICE** Rad & Hem/Onc

**DEPARTMENT** Rad & Hem/Onc

1. Granger E, Hopper K, Diehl L. An Evaluation of Computed Tomography of the Chest in Changing the Stage or Treatment of Patients with Hodgkin's Disease (40 Cases). Presented to the Current Concepts in Internal Medicine Meeting, October, 1985.

There were no publications.

DEPARTMENT OF PRIMARY CARE AND COMMUNITY MEDICINE

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 74/651 (3) Status: Ongoing  
 (4) Title: Establishment of and Training in Methods for Special Studies of Abnormal Hemoglobins

(5) Start Date: January 1974	(6) Est Compl Date: Indefinite
(7) Principal Investigator: Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC

(9) Dept/Svc: Primary Care	(10) Assoc Investigators:
(11) Key Words: Abnormal Hemoglobins Techniques on Identification	Joseph Lima, DAC T. Waldrup, DAC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 12/82 b. Review Results: ongoing  
 c. Number of Subjects Enrolled During Reporting Period: NA  
 d. Total Number of Subjects Enrolled to Date: NA  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". NA

(15) Study Objective:  
 To establish and conduct training in methods for special studies of abnormal hemoglobins.

(16) Technical Approach: To acquaint and to train existing personnel in the performance of various procedures as they pertain to biochemical study of hemoglobins and red cell enzymes involved in hemoglobin function.

(17) Progress: Since 1974 the following can now be performed. Column chromatography; electrophoresis and iso-electrofocusing of hemoglobin; column chromatography and electrophoresis and iso-electrofocusing of globin and electrophoretic demonstration of iso-enzymes of both NADH and NADPH dependent methemoglobin reductases. Quantitation of NDAH-cytochrome b<sub>5</sub> and HADPH MR, glutathione, glutathione reductase now can be done. G-6 PD iso-enzyme patterns now can be determined. Recently equipment for the determination of hemoglobin oxygen dissociation curve has been obtained, and is operational. Carbohydrate and nucleoside utilization of red cells can now be assessed using cold or radioactive substrates, as well as quantitation of erythrocyte glycolytic intermediates, electrofocusing and electrophoresis of adenosine deaminase and of purine nucleoside phosphorylase. Program with quantitation of purine nucleotides and nucleosides has been hampered by shortage of personnel to assist the principal investigator. It is anticipated that work will again begin in FY 86.

CONTINUATION SHEET, FY 85 ANNUAL PROGRESS REPORT

Proto No.: 74/651

Publications: None

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 78-650 (3) Status: Ongoing

(4) Title: Evaluation of Thalassemia as Cause of Hypochromic Microcytic Anemia and in Interaction with Hemoglobin Variants

(5) Start Date: March 1978

(6) Est Compl Date: Indefinite

(7) Principal Investigator:

(8) Facility: FAMC

Nicholas C. Bethlenfalvay, MD, DAC

(9) Dept/Svc: Primary Care

(10) Assoc Investigators:

(11) Key Words:

Thalassemia-hemoglobin variants

Joseph Lima, DAC

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 2/83 b. Review Results: ongoing

c. Number of Subjects Enrolled During Reporting Period: 1

d. Total Number of Subjects Enrolled to Date: 63

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

None.

(15) Study Objective:

To establish phenotype and genotype in patients with microcytic hypochromic anemia due to imbalance in globin chain synthesis.

(16) Technical Approach:

Patients with (a) hypochromic-microcytic anemia (b) patients whose hemoglobin electrophoretogram reveals a variant hemoglobin in amounts greater than 50 or less than 40% will be evaluated. Peripheral blood will be incubated with <sup>14</sup>C leucine. Alpha/beta globin synthetic ratios will be calculated.

(17) Progress: Since the inception of the study, 63 patients were evaluated resulting in the identification of the following conditions: HbC/alpha thalassemia HbS/beta plus thalassemia HbS/beta 0 thalassemia, HbH disease, \*2 cases of acquired HbH disease alpha-thalassemia - 1 and type II normal HbA<sub>2</sub> - beta plus thalassemia. Active consultation is provided, in selected case to the Staff Division of Hematology, University of Colorado Medical Center, Denver, under this protocol. In FY 1983 and in collaboration with investigators at the University of Oxford, U.K., and the University of California, San Francisco, work is continuing on the definition of the molecular lesion in the zeta-alpha globin gene complex of isolated chromosomes #16 of three patients who represent a new syndrome of hemoglobin H disease with mental retardation, and up to now not a described type of congenital dyserythropoietic anemia was published in 1985 with the collaboration of clinicians in Romania and the Federal German Republic.

PUBLICATIONS for FY 85 Annual Progress Report

Proto No. 78-650

SERVICE Clinic

DEPARTMENT DPCCM

PUBLICATIONS:

1. Boehme WM, Piira TA, Kurnick JE and Bethlenfalvay NC: Acquired hemoglobin H in refractory sideroblastic anemia: A preleukemic marker. Arch Int Med, 138:603-606, 1978.
2. Weatherall DJ, Higgs DR, Bunch MB, Old JM, Hunt DM, Pressley L. Clegg JB, Bethlenfalvay NC, Sjolin S, Kiler RD, Magenis E. Francis JL and Bebbington, D: Hemoglobin H disease and mental retardation. A new syndrome or a remarkable coincidence? New Eng J Med 305:607, 1981
3. Bethlenfalvay NC, Hadnagy CSJ Heimpel H: Unclassified Type of Congenital Dyserythropoietic Anemia (CDA) With Prominent Peripheral Erythroblastosis. Brit J. Haemat. 60:541-550, 1985.

PRESENTATIONS:

Bethlenfalvay, N.D., Hadnagy, C and Heimpel, H.: Unclassified type of Congenital Dyserythropoietic Anemia: Evidence for a Disturbance of Red Cell Denucleation. Presented: 20th Annual Meeting of the Hungarian Society of Hematology, Szeged, Hungary, August 1984.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 80/650 (3) Status: Ongoing  
 (4) Title: The Ontogenesis of Hemoglobin in the American Opossum  
 (Didelphis Virginia).

(5) Start Date: 18 March 1980	(6) Est Compl Date: Indefinite
(7) Principal Investigator:  Nicholas C. Bethlenfalvay, MD, DAC	(8) Facility: FAMC

(9) Dept/Svc: Primary Care	(10) Assoc Investigators:
(11) Key Words: Opossum Hemoglobin Red Cell Energy Metabolism Methemoglobin formation & reduction	J.E. Lima, DAC

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: 4/83 b. Review Results: ongoing  
 c. Number of Subjects Enrolled During Reporting Period: NA  
 d. Total Number of Subjects Enrolled to Date: NA  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

NA

(15) Study Objective:  
 This is a continuation of a previous Clinical Investigation study that was completed in June 1975. The overall objective is to follow and define the kinetics of methemoglobin reduction of opossum hemoglobin, in specific, as part of the overall energy metabolism of the red cell of this species.

(16) Technical Approach:  
In-vivo and in-vitro reduction of nitrite induced methemoglobinemia will be followed hourly by quantitative, electrophoretic and spectroscopic means. Methemoglobin reductases will be quantitated and electrophoretically demonstrated, and compared to human reductases.

(17) Progress: Opossum Hb was found to oxidize faster than human Hb in solution, the converse was observed on intact, glucose depleted erythrocytes even at acidic pH. Although opossum red cells were shown to be permeable to glucose, they did not require this substrate for methemoglobin reduction in-vitro methylene blue was found to accelerate methemoglobin reduction on intact opossum erythrocytes at a rate exceeding that seen in human erythrocytes. This reaction, in contrast, was shown to be dependent on glucose in the red cell environment. In FY 1983, work has been completed on the utilization of 6, 5 and 3 C carbohydrates and purine nucleosides as substrates for lactate and ATP in intact erythrocytes. The data were published in FY 1984. Quantitation of red

cell glycolytic intermediates, electrophoretic demonstration of adenosine deaminase and of purine nucleoside phosphorylase was accomplished. In preparation for HPLC analysis of catabolism of purine nucleotides as the putative energy source for methemoglobin reduction on glucose depleted erythrocytes, orienting experiments were performed utilizing various enzyme inhibitors to assess their ability to block this process. Due to late arrival of equipment and personnel shortages there has been no progress on FY 85 on this investigation. It is anticipated that work will start again early in FY 85.

## PUBLICATIONS for FY 85 Annual Progress Report

Proto No. 80-650SERVICE ClinicDEPARTMENT Primary Care & Community  
Medicine

Petty C, Bethlenfalvay NC and Bageant T.: Spectrophotometric measurement of hemoglobin oxygen saturation in the Opossum, *Didelphis Virginiana*. Comp. Biochem Physiol, 50:273, 1975.

Bethlenfalvay NC, Block, M and Brown GB: Hemoglobins of the Opossum (*Didelphis Virginiana* Kerr) I. Developmental changes from yolk sac to definitive erythropoiesis. Lab. Animal Sci, 26:106-165, 1976.

Bethlenfalvay NC, Brown CL and Waterman M: I. Hemoglobins of the Opossum (*Didelphis Marsupialis*) II. Electrophoretic and Chromatographic observations. Lab Animal Sci, 26:908-912, 1976.

John ME, Bethlenfalvay NC and Waterman MR: Oxidation - reduction properties of the hemoglobin of the opossum *Didelphis Virginiana*. Comp. Biochem Physiol. 73B:585-591, 1982.

Bethlenfalvay NC, Waterman MR, Lima JE and Waldrup T: Cystolic and membrane-bound methemoglobin reductases in erythrocytes of the opossum *Didelphis Virginiana*. Comp. Biochem. Physiol. 73B:594, 1982.

Bethlenfalvay NC, Waterman MR, Lima JE, Waldrup T: Comparative aspects of methemoglobin formation and reduction in opossum *Didelphis Virginiana* and human erythrocytes. Comp. Biochem. Physiol. 75A: 635-639, 1983.

Bethlenfalvay NC, Lima JE and Waldrup T: Studies on the energy metabolism of opossum (*Didelphis Virginiana*) erythrocytes. I. Utilization of carbohydrates and purine nucleosides. Journal of Cellular Physiology. 120:69-74, 1984.

DEPARTMENT OF NURSING

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/700 (3) Status: Completed  
(4) Title: A Comparison of Fluid Assessment Methods Utilizing Central Venous Pressure Versus Serum Osmolarity in Conjunction with Conventional Methods in Adults Undergoing Abdominal Surgery.

(5) Start Date: 1983	(6) Est Compl Date: Completed
(7) Principal Investigator: Cynthia Bernard, CPT, ANC Michael Buxton, CPT, ANC James Eiring, CPT, ANC Donald Johnson, CPT, ANC Richard Palley, CPT, ANC Gregory Whitfield, CPT, ANC	(8) Facility: FAMC

(9) Dept/Svc: Nursing	(10) Assoc Investigators:
(11) Key Words: comparison of fluid assessment methods	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period:  
d. Total Number of Subjects Enrolled to Date: 40  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: There is no difference in calculated intraoperative fluid requirements as determined by CVP and conventional methods versus serum osmolarity and conventional methods.

(16) Technical Approach: The need for fluid replacement intraoperatively was made using the central venous pressure reading and other conventional fluid assessment parameters. Serum osmolarities were drawn during the surgical procedure and retrospectively evaluated to determine if serum osmolarities would provide a better means of calculating fluid replacement in the surgical patient.

(17) Progress: Study is now completed with data being analyzed for publication.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/700 (3) Status: Completed

(4) Title: The Effects of Preoperative Hydration During Induction of General Anesthesia for the Hypertensive Patient

(5) Start Date: March 85

(6) Est Compl Date: Complete

(7) Principal Investigator:  
Dewey Galeas, CPT

(8) Facility: FAMC

(9) Dept/Svc: Anesthesia

(10) Assoc Investigators:

(11) Key Words:  
hypertension  
prehydration

Michael Cook, CPT  
Donald Heon, CPT

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_

c. Number of Subjects Enrolled During Reporting Period: 20

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine the effects on cardiovascular stability of prehydration of hypertensive, elective general surgery patients on diuretic therapy, versus the accepted approach of maintaining surgical patients NPO the night before surgery.

(16) Technical Approach: Randomly selected patients (Informed consent) were divided into two groups. One group had intravenous solutions started the night before surgery, the other group held NPO. Using a Dinemapp #847 monitor, blood pressure and pulse in response to general anesthesia were recorded.

(17) Progress: Data collection has been completed as of 1 September 1985. The data are presently being analyzed for write up.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/701 (3) Status: Completed  
 (4) Title: Use of the Emergency Department in an Army Hospital  
 by Patients with Nonurgent Conditions

(5) Start Date: 11 May 1985 (6) Est Compl Date: 24 May 1985  
 (7) Principal Investigator: Lois J. Dickinson, CPT,  
 ANC (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Assoc Investigators: None  
 (11) Key Words: Emergency Department, Use  
 Nonurgent Conditions

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*  
 \*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:  
 c. Number of Subjects Enrolled During Reporting Period: 100  
 d. Total Number of Subjects Enrolled to Date: 100  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To investigate factors which contribute to overutilization of the Emergency Department by patients in an Army hospital.

(16) Technical Approach: This study was a nonexperimental, descriptive study which used the survey method for data collection. One hundred patients who used the ED for treatment of nonurgent conditions were interviewed, following the format of the questionnaire.

(17) This study has been completed and has met the requirements for my thesis study for the degree of Master of Science of Emergency Nursing at the University of Texas Health Science in Houston.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 85/702 (3) Status: Terminated	
(4) Title: The Impact of Decisional Control on Patient Satisfaction and Selected Health Care Outcomes	
(5) Start Date: 1975	(6) Est Compl Date: Terminate
(7) Principal Investigator: Valerie E. Biskey, MAJ, RN	(8) Facility: FAMC Fort Carson, Colorado
(9) Dept/Svc: Nursing	(10) Assoc Investigators:
(11) Key Words:	
(12) Accumulative MEDCASE:*	(13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this report.	
(14) a. Date, Latest HUC Review: b. Review Results:	
c. Number of Subjects Enrolled During Reporting Period:	
d. Total Number of Subjects Enrolled to Date:	
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".	
(15) Study Objective: To determine if patient participation in health care decisions is related to increased satisfaction with health care, changes in blood pressures, and/or increased weight loss.	
(16) Progress: Due to the principal investigator's failure to reply the study is terminated. Study was designed to fulfill graduate requirements.	

FAMC TENANT

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/800 (3) Status: Completed  
 (4) Title: The Health Evaluation Project of the OCHAMPUS Employee Health Promotion Program

(5) Start Date:	(6) Est Compl Date:
(7) Principal Investigator: William H. Hendrix, Ph.D.	(8) Facility: FAMC

(9) Dept/Svc: OCHAMPUS	(10) Assoc Investigators: Alex R. Rodriguez, M.D.
(11) Key Words: health promotion, wellness job satisfaction, production somatic symptoms, stress emotional exhaustion	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
 c. Number of Subjects Enrolled During Reporting Period: \_\_\_\_\_  
 d. Total Number of Subjects Enrolled to Date: 235  
 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e").

(15) Study Objective: To establish what individual, organizational and extra-organizational factors are predictive of stress, coronary artery disease potential, and desired organizational outcomes-i.e., increased productivity and decreased turnover and absenteeism. In turn, modification of these factors and their resulting effects will be assessed over time from the identified dependent variables (measured stress, indexed potential for developing CAD, and desired organizational outcomes).

(16) Technical Approach: Evaluation of data will be in the form of path analyses to establish relationships between factors leading to stress and in turn to health-related and organizational factors. A pretest, post-test design is being used to establish effectiveness of interventions employed such as stress management and exercise.

(17) Progress: Study is now complete with final summary forwarded to the Department of Clinical Investigation.

**PRESENTATIONS FOR FY 85 Annual Progress Report**

**Proto No. 83/800**

**SERVICE N/A**

**DEPARTMENT N/A**

1. Hendrix, W.H., and Rodriquez, A.R.: Effects of Stress on Individual Productivity Absenteeism, and Wellness. Presented: Ninth Biennial Psychology in the DOD Symposium, USAFA, Colorado, April 1984.
2. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Effects of Stress and Exercise on Employee Health. Presented: Fifth Annual Meeting of the Society of Behavioral Medicine, Philadelphia, Pa., May 1984.
3. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Job and Personal Factors Related to Job Stress and Risk of Developing Coronary Artery Disease. Presented: American Industrial Hygiene Conference, Detroit, Michigan, May 1984.
4. Hendrix, W.H., Rodriquez, A.R., and Presley, A.: Stress Effect on Organizational Outcomes and Prediction of CAD Risk. Presented: 92nd Annual American Psychological Association Convention, Toronto, Canada, August 1984.
5. Rodriquez, A.R., Iverson, D.C., Hendrix, W.H., Presley, A.: An Employee-Directed Wellness Project: Early Findings from the OCHAMPUS Health Promotion Program. Presented: American Public Health Association Meeting, Dallas, Texas, November 1983.

MEDDAC

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/902 (3) Status: Ongoing

(4) Title: Training Study, Emergency Medical Procedures

(5) Start Date: Nov 1982

(6) Est Compl Date: Indefinite

(7) Principal Investigator:  
MATTHEW J. WALSH, LTC, MC

(8) Facility:  
Ft Carson Veterinary Activity and  
Ft Carson MEDDAC Emergency Medical  
Service

(9) Dept/Svc: Emer Med & Vet

(10) Assoc Investigators:

(11) Key Words:  
Emergency Medicine

LTC David Roberts, MC

(12) Accumulative MEDCASE:\* ☒ (13) Est Accum OMA Cost:\* ☒  
\*Refer to Unit Summary Sheet of this report.

- (14) a. Date, Latest HUC Review: \_\_\_\_\_ b. Review Results: \_\_\_\_\_  
c. Number of Subjects Enrolled During Reporting Period: N/A  
d. Total Number of Subjects Enrolled to Date: N/A  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: This project is a refresher/teaching course in Emergency Medicine operative procedures. It is conducted on a quarterly basis for EMS physicians and PA's.

(16) Technical approach: Under general anesthesia animals are subjected to common Emergency Medicine operative procedures, including venous cutdown, peritoneal lavage, chest tube insertion, and thorocotomy with aortic cross clamp with cardiac laceration repair. At the end of the exercise, the animals are killed by lethal injection.

(17) Progress: This has been a beneficial exercise in maintaining physical skills in technical procedures done infrequently. These skills are essential for good patient care in true emergencies.

Publications and presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-25, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 83/904 (3) Status: Terminated  
(4) Title: Activated Charcoal and Phototherapy in the Treatment of Neonatal Jaundice

(5) Start Date: 1983	(6) Est Compl Date:
(7) Principal Investigator: Stephen Inscore, M.D.	(8) Facility: FAMC Munson Army Community Hospital

(9) Dept/Svc: Pediatrics	(10) Assoc Investigators:
(11) Key Words: charcoal jaundice	

(12) Accumulative MEDCASE:\* (13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HBC Review: b. Review Results:  
c. Number of Subjects Enrolled During Reporting Period: 2  
d. Total Number of Subjects Enrolled to Date: 3  
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To examine the effectiveness of oral activated charcoal has in limiting the severity of nonphysiologic hyperbilirubinemia in otherwise normal newborns treated with phototherapy.

(16) Technical Approach: Term newborns who are otherwise normal except for non-physiologic jaundice will be alternately placed into a group receiving phototherapy alone and in combination with charcoal. Parameters will be measured to determine if the combination of charcoal and phototherapy will enhance elimination of bilirubin.

(17) Progress: Due to my upcoming assignment and no one to assume the study and too few numbers, the study is hereby terminated.

CIVILIAN HOSPITALS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (Ref. HSCR 40-23, as amended)

(1) Date: 30 Sep 85 (2) Protocol WU#: 84/951 (3) Status: Ongoing

(4) Title:

Childhood Cancer and Electromagnetic Field Exposures

(5) Start Date: 12/1/83

(6) Est Compl Date: 6/30/86

(7) Principal Investigator:

(8) Facility: FAMC

David A. Savitz, Ph.D.  
Assistant Professor  
Dept. Prev. Med. & Biom.  
Univ. Colo School of Med.

(9) Dept/Svc: (NOT AT FAMC)

(10) Assoc Investigators:

(11) Key Words:

Childhood Cancer  
Electromagnetic Fields  
Nonionizing Radiation

Frank Barnes, Ph.D.  
Richard F. Hamman, M.D., Dr.P.H.  
Richard H. Jones, Ph.D.  
Lorrie F. Odom, M.D.  
Howard Wachtel, Ph.D.

(12) Accumulative MEDCASE:\*

(13) Est Accum OMA Cost:\*

\*Refer to Unit Summary Sheet of this report.

(14) a. Date, Latest HUC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 250

d. Total Number of Subjects Enrolled to Date: 250

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. (May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine whether there is an association between risk of cancer in children and exposure to high levels of electromagnetic fields in homes.

(16) Technical Approach: This is a case-control study in which residential exposure histories of children with cancer will be contrasted to exposure histories of controls. Exposure is based on in-home measurements and coding of wiring configuration near the home.

(17) Progress: During the period October 1, 1984 through September 30, 1985, a total of 400 interviews will have been completed. This includes 240 cases and 160 controls. (Only 5 cases were identified through FAMC record review.) All data collection will be complete by December 31, 1985, with data analysis to be done during the first half of 1986. There have been no presentations or publications from this study.

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